United States Food and Drug Administration (FDA) Medical Device Classification System

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WHITE PAPER

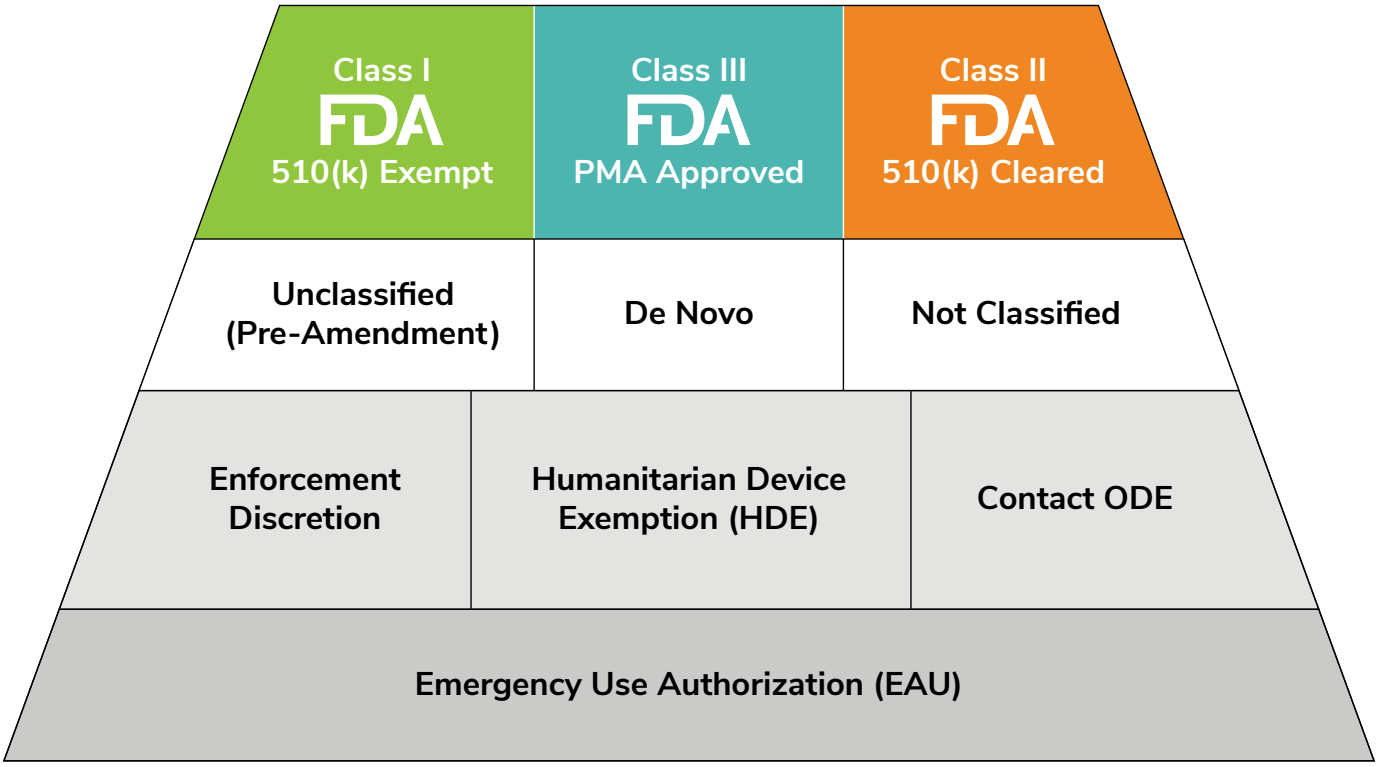
What you will learn in this white paper

- **History of medical device classification in the U.S.**
- **FDA medical device classification system**
- **Classifying your medical device and some helpful tips in the process**

Medical device classification in the U.S.

In 1976, the Medical Device Amendments were added to the United States (U.S.) Federal Food, Drug and Cosmetic Act (FD&C Act) of 1938, establishing the current risk-based classification system for all medical devices the FDA regulates. The Medical Device Amendments were intended to provide reasonable assurance of the safety and effectiveness of all medical devices.

The Medical Device Amendments also established that, for devices that were not on the market prior to passage of the amendments on May 28, 1976 — aka pre-amendment devices — or for devices that had been significantly modified, a premarket notification (510(k)), De Novo or premarket approval (PMA) pathway would be required to place these higher-risk devices on the market.



The FDA medical device classification system

Knowing the correct classification of your medical device is crucial for mapping its regulatory route to commercialization in the U.S. How the FDA classifies a medical device depends on the level of risk and Regulatory Controls appropriate to control the risk the device poses to the intended patient and user(s) – e.g., lay users, healthcare professionals, and caregivers. The risks and regulatory controls applicable to a medical device are specific to its intended use, indications for use and technological characteristics as these things can influence the time and costs of bringing your device to market. Higher-risk devices are significantly more costly and take longer to bring to market than lower-risk devices.

There are three main classes of medical devices in the U.S. (Class I, Class II, and Class III) in addition to "unclassified" (aka pre-amendment devices), "not classified" and "humanitarian device exemption" (HDE) devices. Every medical device type has a unique three-letter product code and name attached to it. The FDA[1] currently has approximately 6,500 product codes assigned that reside within the different Device Classification Panels found in Parts 862-892 of the Code of Federal Regulations (CFR), for which the FDA has also established more than 1,700 seven-digit regulation numbers to describe the different device types. The number of product codes increases every year.

Class I devices are low-risk, only require general controls and typically do not require 510(k) clearance from the FDA under a premarket notification, as most of these devices are 510(k)-exempt. However, there are some Class I devices that do require 510(k) clearance.

Class II devices are moderate-risk and require general and special controls and 510(k) clearance from the FDA. However, there are some Class II devices that do not require 510(k) clearance.

Note that for those Class I and Class II devices that the FDA has exempted from the 510(k) requirements as described on the product classification page for the related product code, if the device exceeds the limitations of device exemptions covered under 21 CFR XXX.9, where XXX represents the review panel number — e.g., 872 Dental — a 510(k) may be required and the specific parts of XXX.9 (a, b, c) should be reviewed to confirm their relevance. As described in XXX.9, (a) is for a different intended use; (b) is for a different fundamental scientific technology; and (c) is for in vitro diagnostic (IVD) devices, with certain stipulations as described in the regulation.

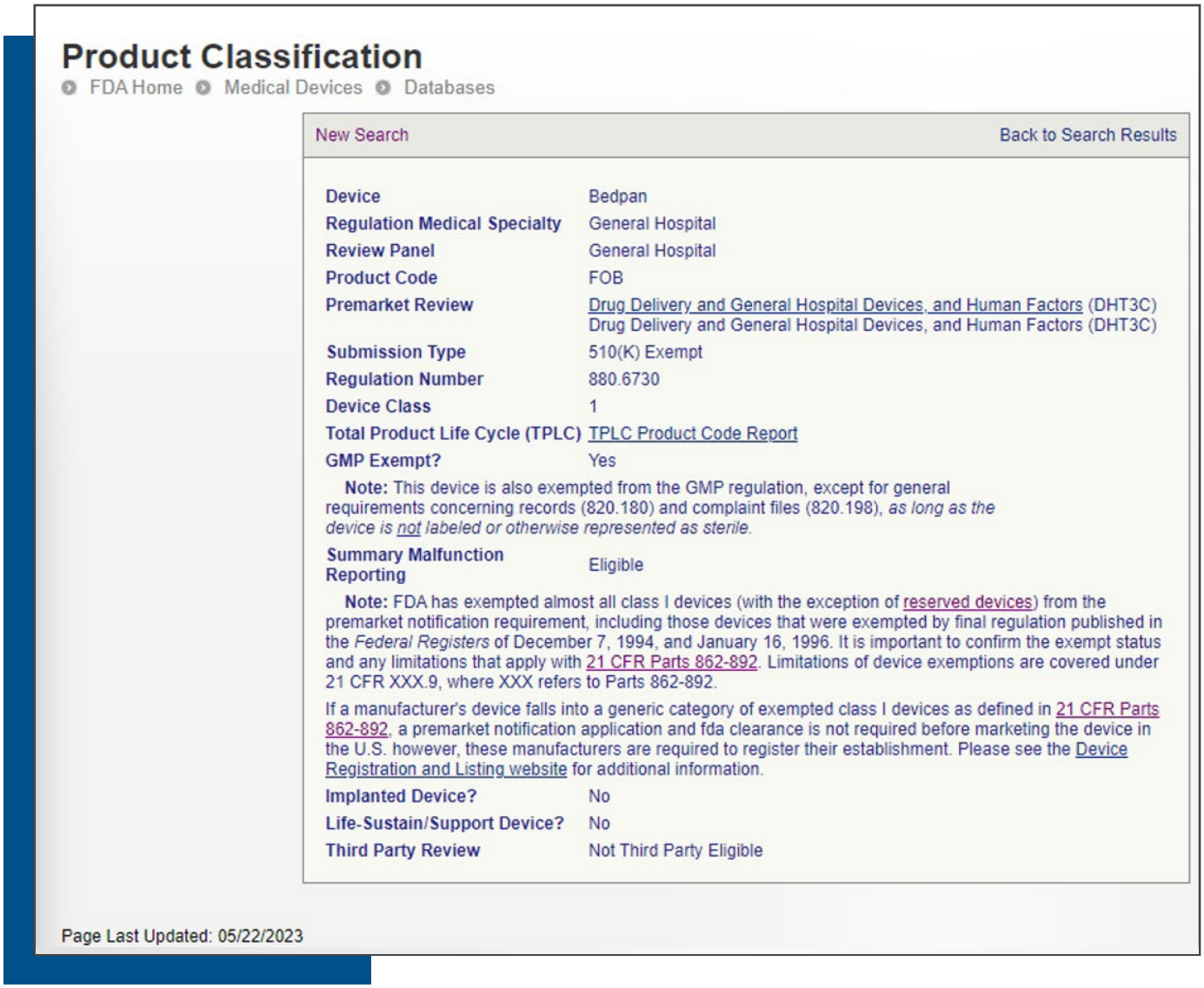
Class III devices entail the highest risk and require general controls and approval from the FDA under a PMA application. These devices require clinical data to provide the FDA with adequate assurance of safety and effectiveness.

For devices that are not high-risk but for which no legally marketed predicate device exists, a De Novo submission can be made to the FDA. Under a De Novo pathway, the FDA will reclassify the device as either Class I or Class II, for which general controls of the FD&C Act apply, as well as device-specific special controls agreed to by the FDA and the device sponsor for Class II devices. Once a De Novo has been granted for the new device and assigned a DEN number, e.g., DEN123456, the FDA assigns a new product code and may assign a new regulation number into the federal register, allowing the device to be sold on the market. The new device can then be used as a predicate device for subsequent submissions under a 510(k).

It is important to remember that, while each medical device has a three-letter product code assigned to it and there are more than 6,500 product codes in the FDA product classification database, there are approximately 1,700[1] regulation numbers. Therefore, there are many examples where multiple product codes fall within the same regulation number. In some cases, there are more than 50 product codes assigned to the same regulation number. This makes selecting the correct product code challenging, as further discussed in this white paper. In addition, there are many devices for which no regulation has been established.

Figures 1-8 show the product classification pages for selected Class I, Class II and Class III devices, as well as for unclassified, not classified and HDE devices, to give the reader some basic familiarity with the type of regulatory information that the FDA includes on these pages, which differs depending on the device's classification, as seen in the following examples.

Figure 1 – Class I Device Product Classification Page — Product Code FOB (Bedpan)



Product Classification

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Device	Bedpan
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	FOB
Premarket Review	Drug Delivery and General Hospital Devices, and Human Factors (DHT3C) Drug Delivery and General Hospital Devices, and Human Factors (DHT3C)
Submission Type	510(K) Exempt
Regulation Number	880.6730
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	Yes

Note: This device is also exempted from the GMP regulation, except for general requirements concerning records (820.180) and complaint files (820.198), *as long as the device is not labeled or otherwise represented as sterile.*

Summary Malfunction Reporting	Eligible

Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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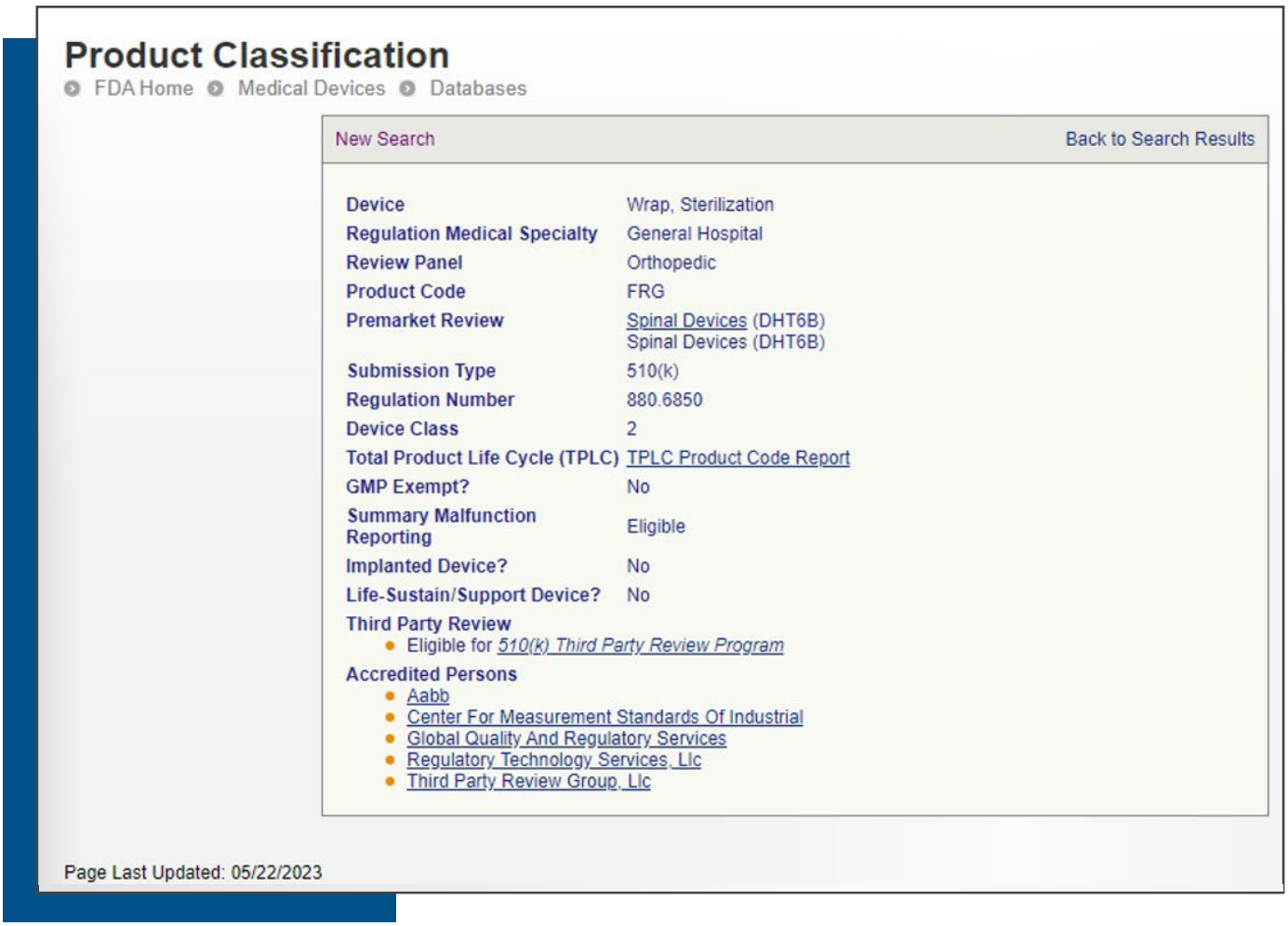
Figure 2 – Class II Device Product Classification Page — Product Code FRG (Wrap, Sterilization)



Product Classification

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Device	Wrap, Sterilization
Regulation Medical Specialty	General Hospital
Review Panel	Orthopedic
Product Code	FRG
Premarket Review	Spinal Devices (DHT6B) Spinal Devices (DHT6B)
Submission Type	510(k)
Regulation Number	880.6850
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	No
Life-Sustain/Support Device?	No

Third Party Review

- Eligible for *510(k) Third Party Review Program*

Accredited Persons

- Aabb
- Center For Measurement Standards Of Industrial
- Global Quality And Regulatory Services
- Regulatory Technology Services, Llc
- Third Party Review Group, Llc

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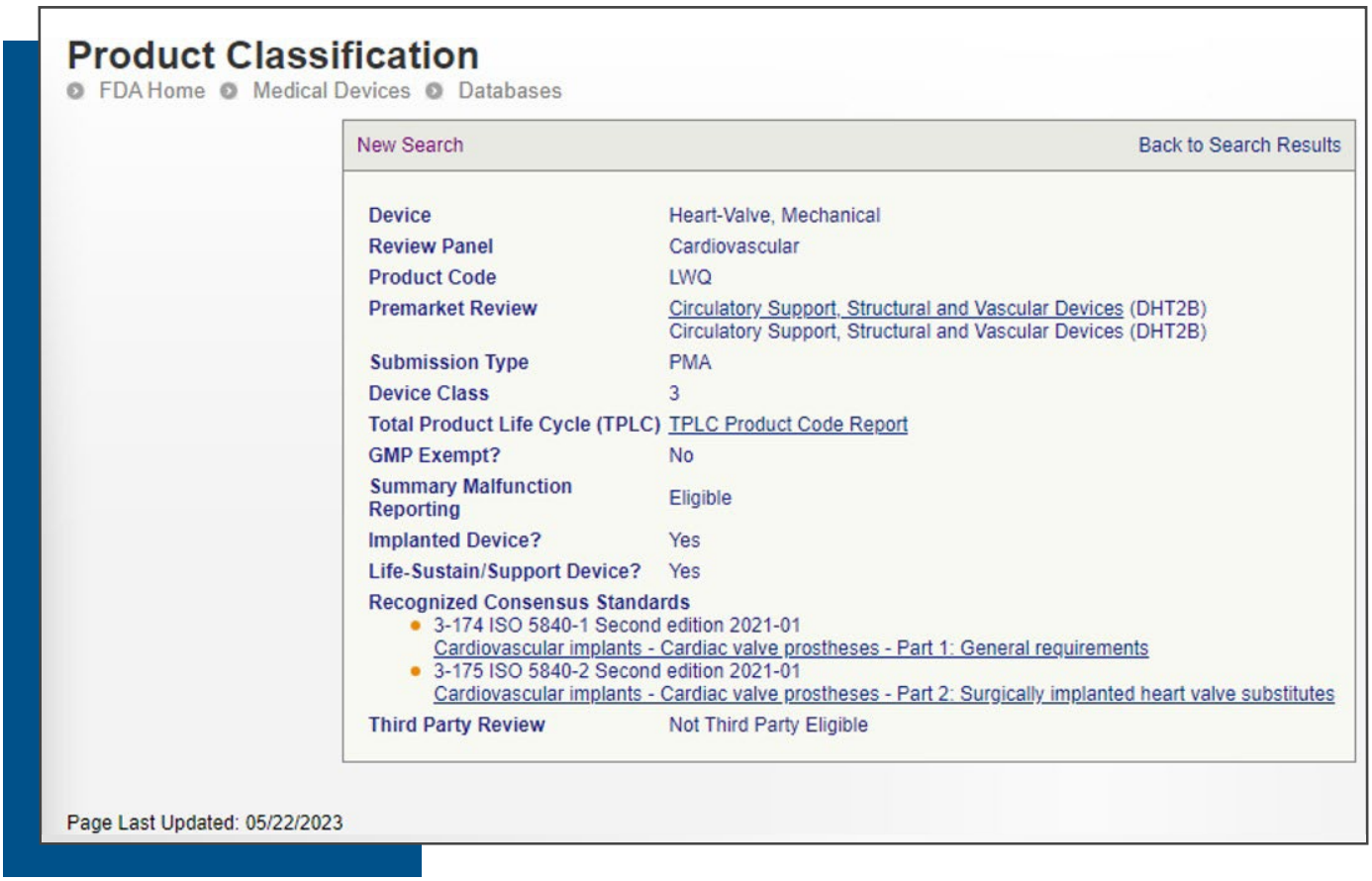
Figure 3 – Class III Device Product Classification Page — Product Code LWQ (Heart-Valve, Mechanical)



Product Classification

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Device	Heart-Valve, Mechanical
Review Panel	Cardiovascular
Product Code	LWQ
Premarket Review	Circulatory Support, Structural and Vascular Devices (DHT2B) Circulatory Support, Structural and Vascular Devices (DHT2B)
Submission Type	PMA
Device Class	3
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	Yes
Life-Sustain/Support Device?	Yes
Recognized Consensus Standards	• 3-174 ISO 5840-1 Second edition 2021-01 Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements • 3-175 ISO 5840-2 Second edition 2021-01 Cardiovascular implants - Cardiac valve prostheses - Part 2: Surgically implanted heart valve substitutes
Third Party Review	Not Third Party Eligible

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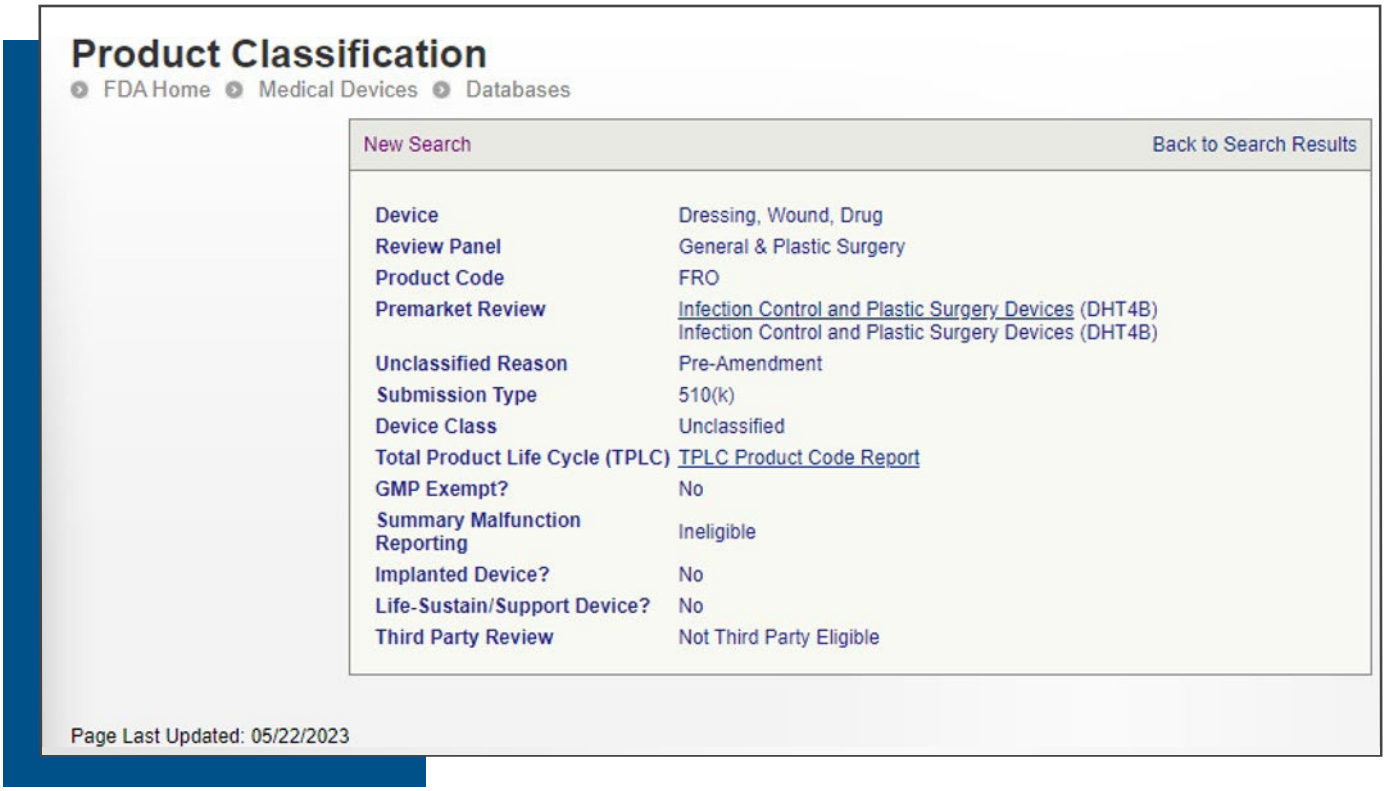
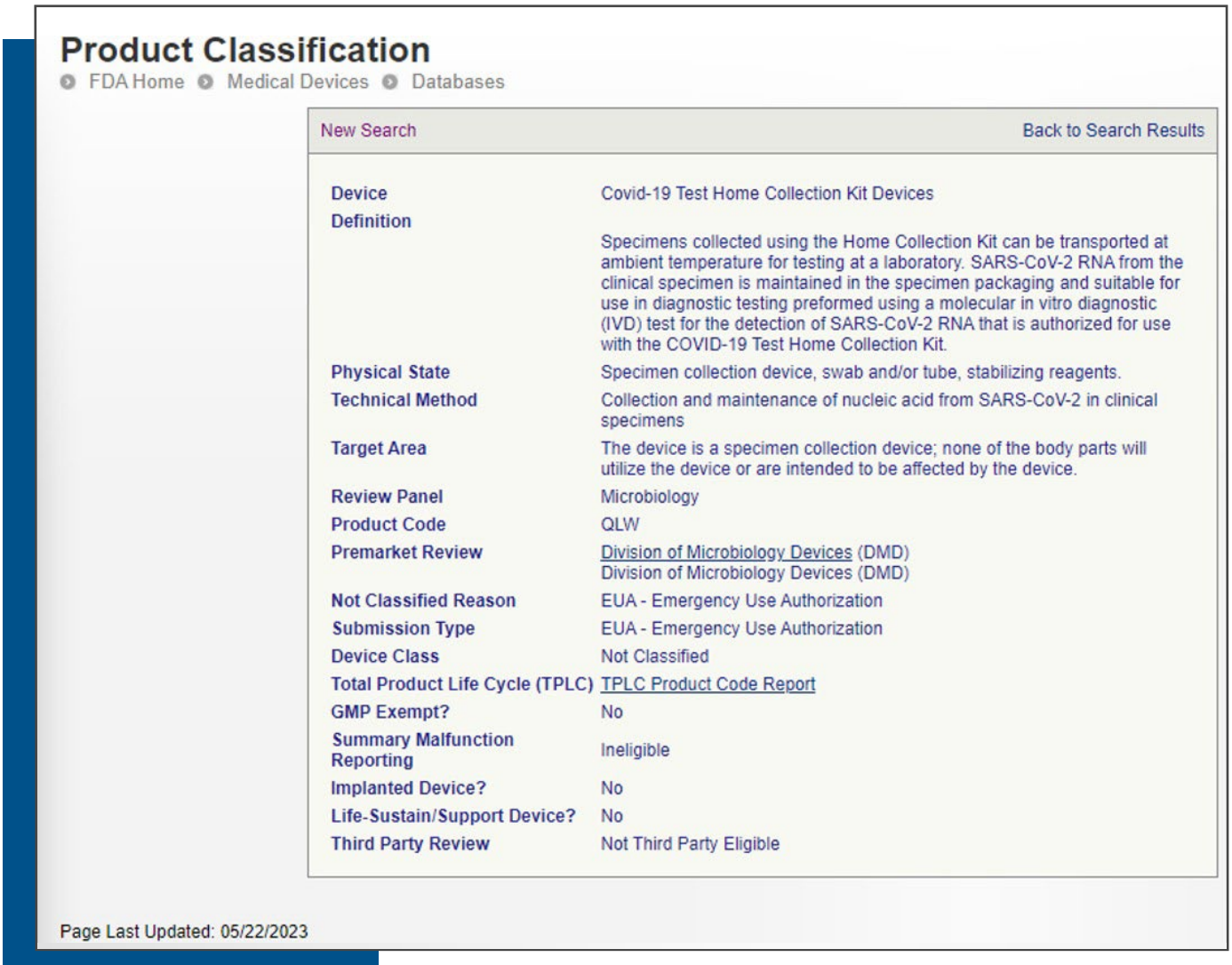
Unclassified or pre-amendment devices are devices that existed before the establishment of the medical device regulations on May 28, 1976. There are 85[1] product codes for these devices, and none of them has a class (Class I, II or III) or regulation number (CFR 123.4567) assigned, as seen in **Figure 4**, using product code FRO as an example. Most unclassified devices require 510(k) clearance, while some are under enforcement discretion as defined on their product classification page for submission type. For product code FRO, the submission type is a 510(k).

Figure 4 – Unclassified Device Product Classification Page — Product Code FRO (Dressing, Wound, Drug)



Not-classified devices are post-amendment devices, and many of them are under emergency use authorization (EUA), enforcement discretion (ED) or for export only (FEO). There are currently 369[1] product codes for these devices, and none of them has a class or regulation number assigned, as seen in **Figures 5-7** for product codes QLW, PFU and PRF, respectively.

Figure 5 – Not Classified Device Product Classification Page — Product Code QLW (Covid-19 Test Home Collection Kit Devices), Under Emergency Use Authorization



Product Classification

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Device	Covid-19 Test Home Collection Kit Devices
Definition	Specimens collected using the Home Collection Kit can be transported at ambient temperature for testing at a laboratory. SARS-CoV-2 RNA from the clinical specimen is maintained in the specimen packaging and suitable for use in diagnostic testing preformed using a molecular in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 RNA that is authorized for use with the COVID-19 Test Home Collection Kit.
Physical State	Specimen collection device, swab and/or tube, stabilizing reagents.
Technical Method	Collection and maintenance of nucleic acid from SARS-CoV-2 in clinical specimens
Target Area	The device is a specimen collection device; none of the body parts will utilize the device or are intended to be affected by the device.
Review Panel	Microbiology
Product Code	QLW
Premarket Review	Division of Microbiology Devices (DMD) Division of Microbiology Devices (DMD)
Not Classified Reason	EUA - Emergency Use Authorization
Submission Type	EUA - Emergency Use Authorization
Device Class	Not Classified
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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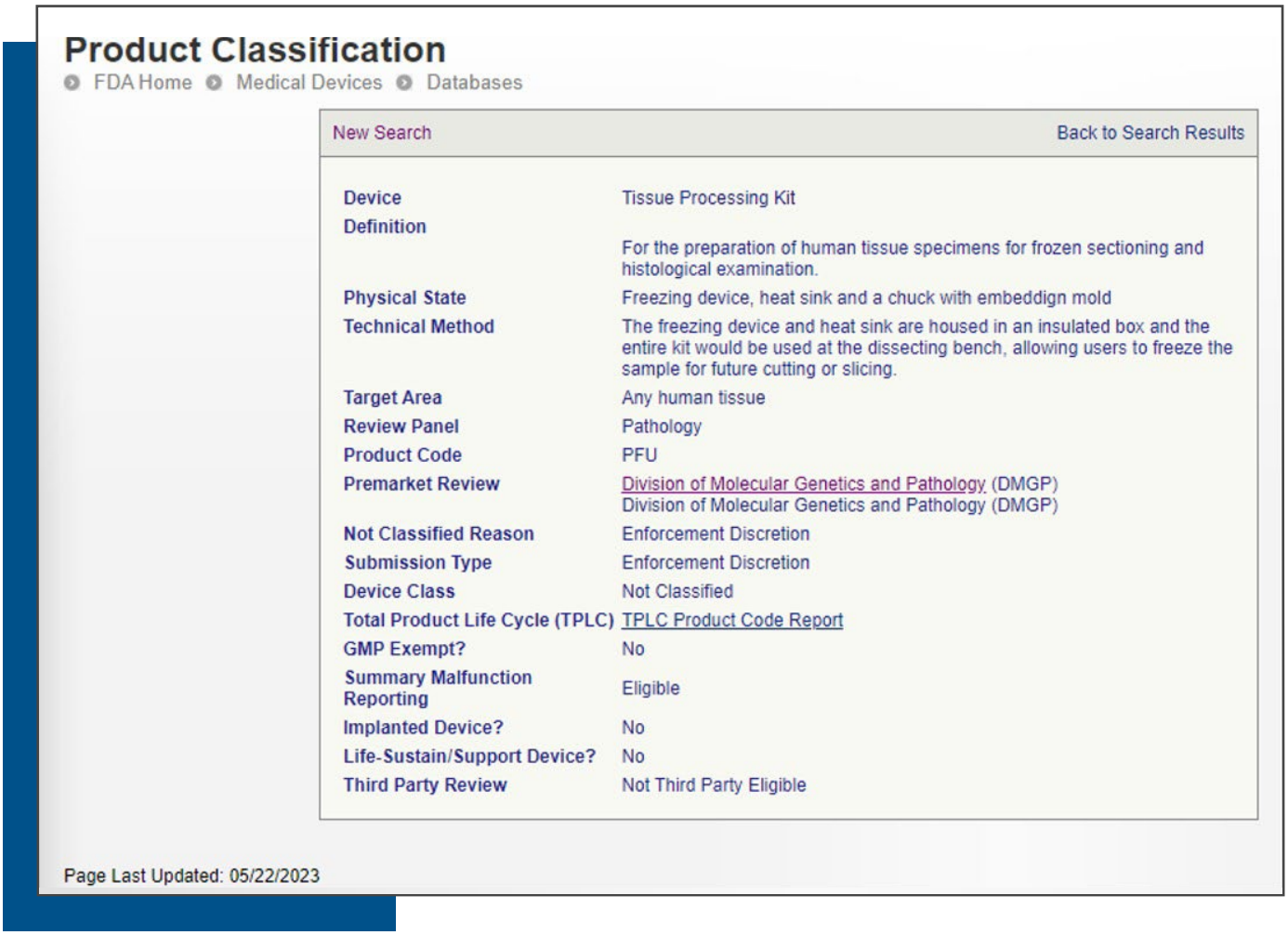
Figure 6 – Not Classified Device Product Classification Page — Product Code PFU (Tissue Processing Kit), Under Enforcement Discretion



Product Classification

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Device	Tissue Processing Kit
Definition	For the preparation of human tissue specimens for frozen sectioning and histological examination.
Physical State	Freezing device, heat sink and a chuck with embeddign mold
Technical Method	The freezing device and heat sink are housed in an insulated box and the entire kit would be used at the dissecting bench, allowing users to freeze the sample for future cutting or slicing.
Target Area	Any human tissue
Review Panel	Pathology
Product Code	PFU
Premarket Review	Division of Molecular Genetics and Pathology (DMGP) Division of Molecular Genetics and Pathology (DMGP)
Not Classified Reason	Enforcement Discretion
Submission Type	Enforcement Discretion
Device Class	Not Classified
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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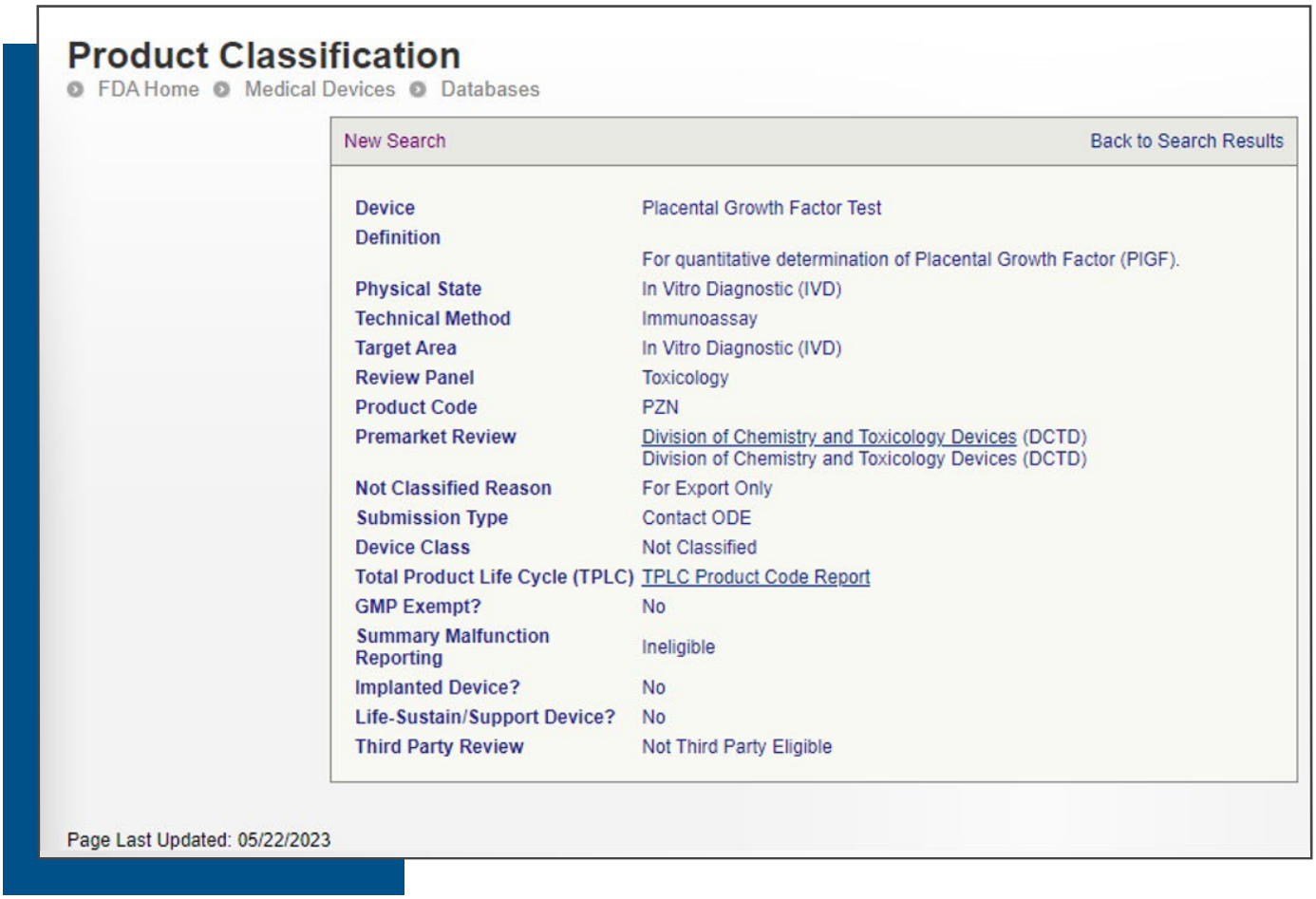
Figure 7 – Not Classified Device Product Classification Page — Product Code PZN (Placental Growth Factor Test), For Export Only



Product Classification

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Device	Placental Growth Factor Test
Definition	For quantitative determination of Placental Growth Factor (PlGF).
Physical State	In Vitro Diagnostic (IVD)
Technical Method	Immunoassay
Target Area	In Vitro Diagnostic (IVD)
Review Panel	Toxicology
Product Code	PZN
Premarket Review	Division of Chemistry and Toxicology Devices (DCTD) Division of Chemistry and Toxicology Devices (DCTD)
Not Classified Reason	For Export Only
Submission Type	Contact ODE
Device Class	Not Classified
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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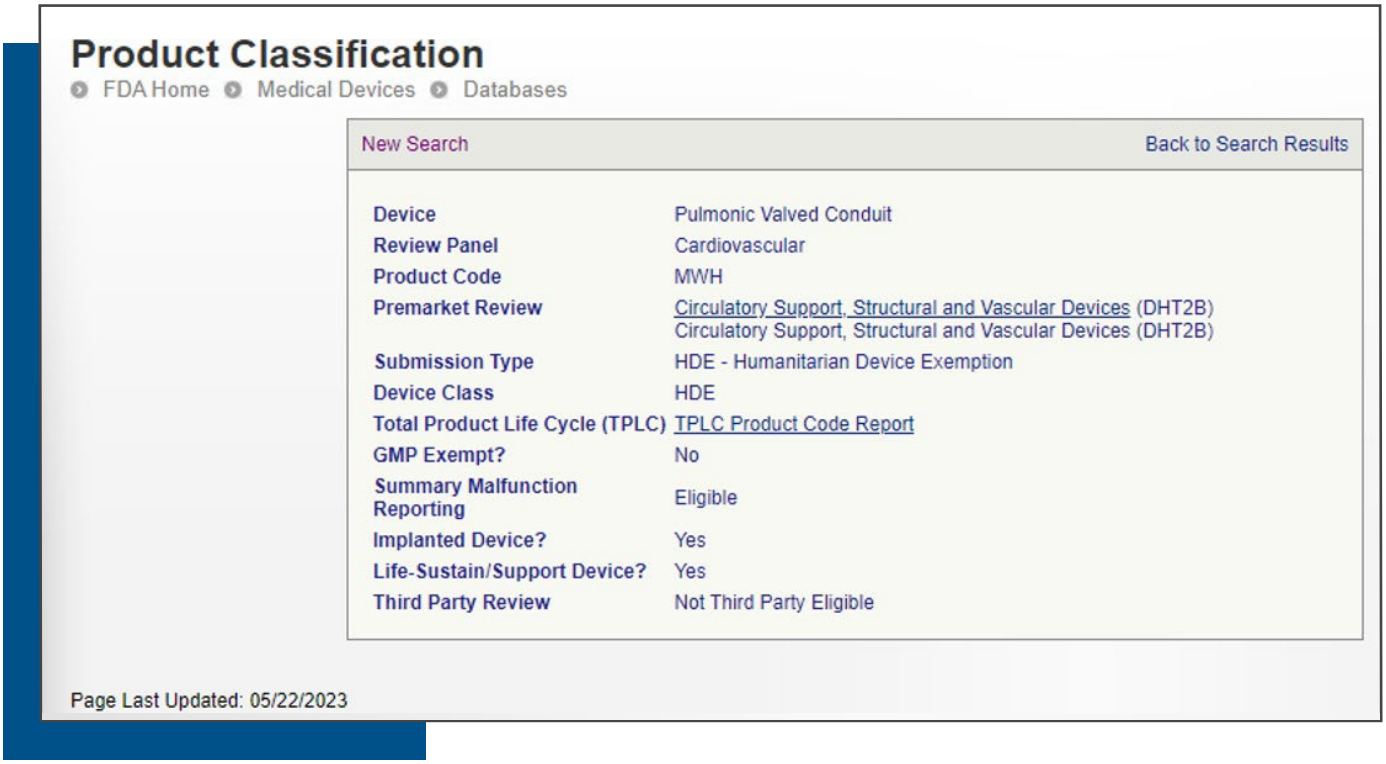
A humanitarian device exemption (HDE) is a marketing application for a humanitarian use device (HUD). A HUD is a medical device intended to benefit patients undergoing treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the U.S. per year. There are currently 48[1] product codes for these devices, as seen in **Figure 8** for product code MWH.

Figure 8 – HDE Device Product Classification Page — Product Code MWH (Pulmonic Valved Conduit)



Classifying your medical device

With a basic understanding of the various categories the FDA uses to classify medical devices as described above, there are many different ways to classify a medical device using certain FDA databases. Those databases are linked below. There are times when a certain database will prove more helpful than another, and in some cases, using more than one database will help further confirm your device's classification to another legally marketed device in the U.S., based on its intended use and technological characteristics.

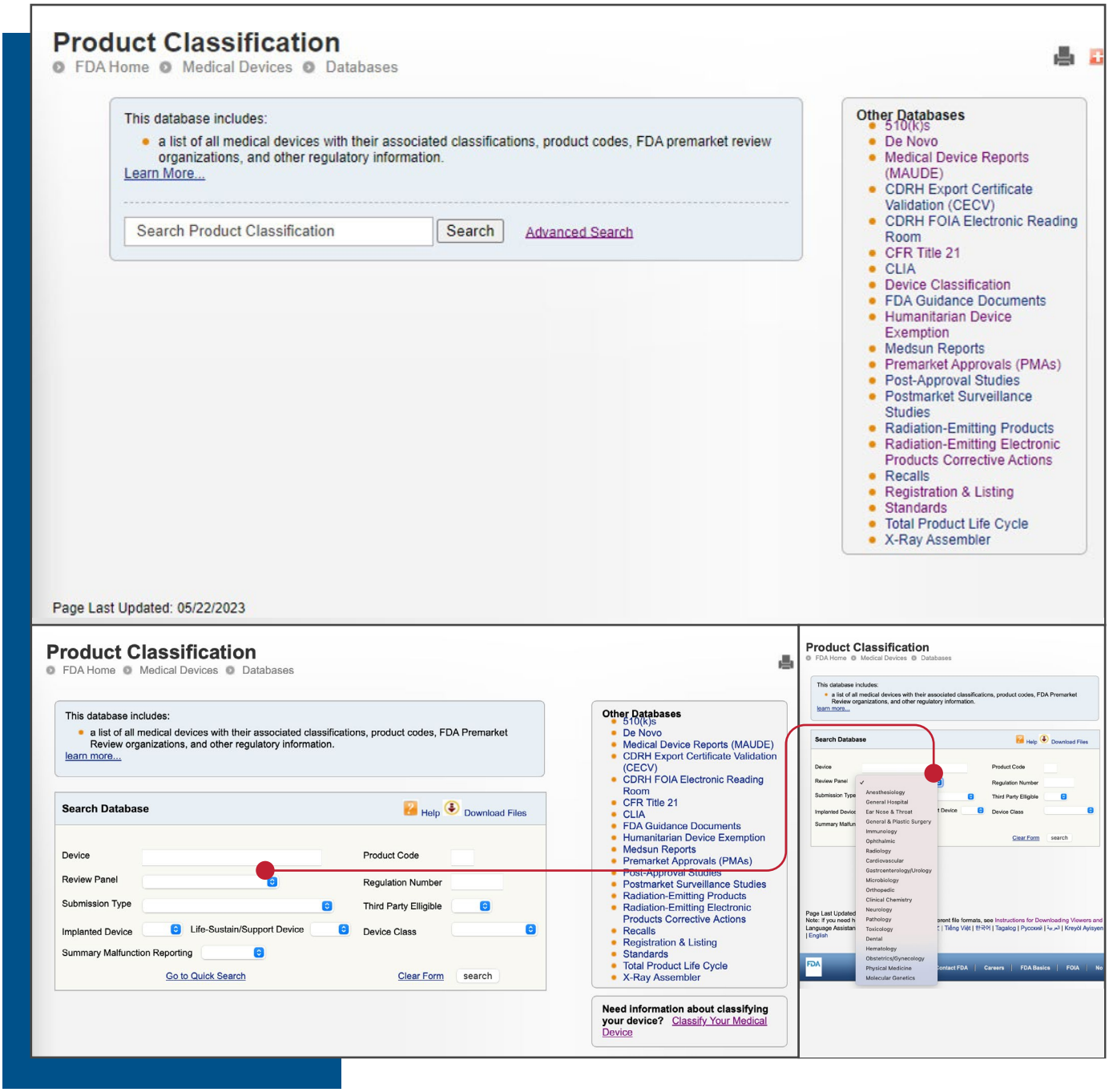
- The Product Classification database
- The Registration & Listing database
- The 510(k) database
- The De Novo database
- The PMA database
- The HDE database

The FDA Product Classification database

The FDA Product Classification database is best used if you are unsure how your device should be classified based on its intended use and technological characteristics. When using this database, you should select keywords that are specific to your device with respect to its intended use and technology as an initial starting point to see what product codes and regulation numbers are extracted from the database.

There are two options for using the Product Classification database as seen in **Figure 9**: the Quick Search option (top) and the Advanced Search option (bottom). Using the advanced search option allows for more customization in your search as you can use other drop-down menus — e.g., review panel, implanted device, etc., as seen below — besides using just the Device field. This can help focus your search efforts beyond what you are limited to when using the Quick Search option.

Figure 9 – Product Classification Database — Quick Search Option (Top) vs. Advanced Search Option (Bottom)



It is important to note that using the same word(s) in the Quick Search and Advanced Search options will often produce a different number of product codes, as seen in **Table 1** and **Figure 10** when using "catheter," "condom," "shoulder prosthesis," "infusion pump" and "artificial intelligence" as some examples.

Table 1 – Product Classification Database Comparison — Quick Search Option vs. Advanced Search Option

Search word(s)	Quick search results	Advanced search results
Catheter	269	262
Condom	11	12
Shoulder prosthesis	11	14
Infusion pump	27	22
Artificial intelligence	9	1

Let us look at three different examples from Table 1.

Classification Example 1 – Condom devices

The figure below shows the subtle differences when using the Quick Search option and Advanced Search option for the word "condom." It is also important not to confuse the product code name with the regulation number name, although they can often be the same, as seen below.

Figure 10 – Product Classification Database Comparison — Quick Search Option (Top) vs. Advanced Search Option (Bottom) for "Condom"

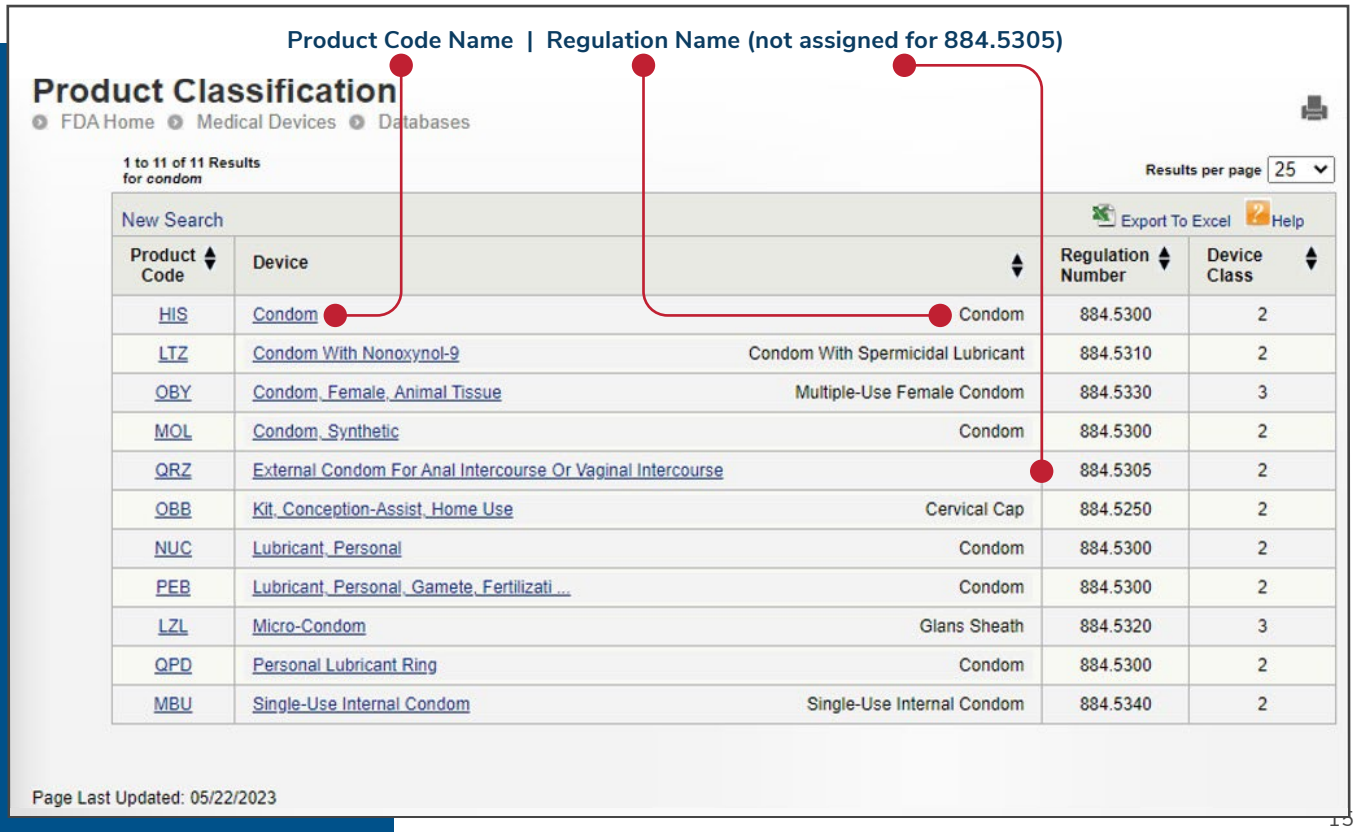
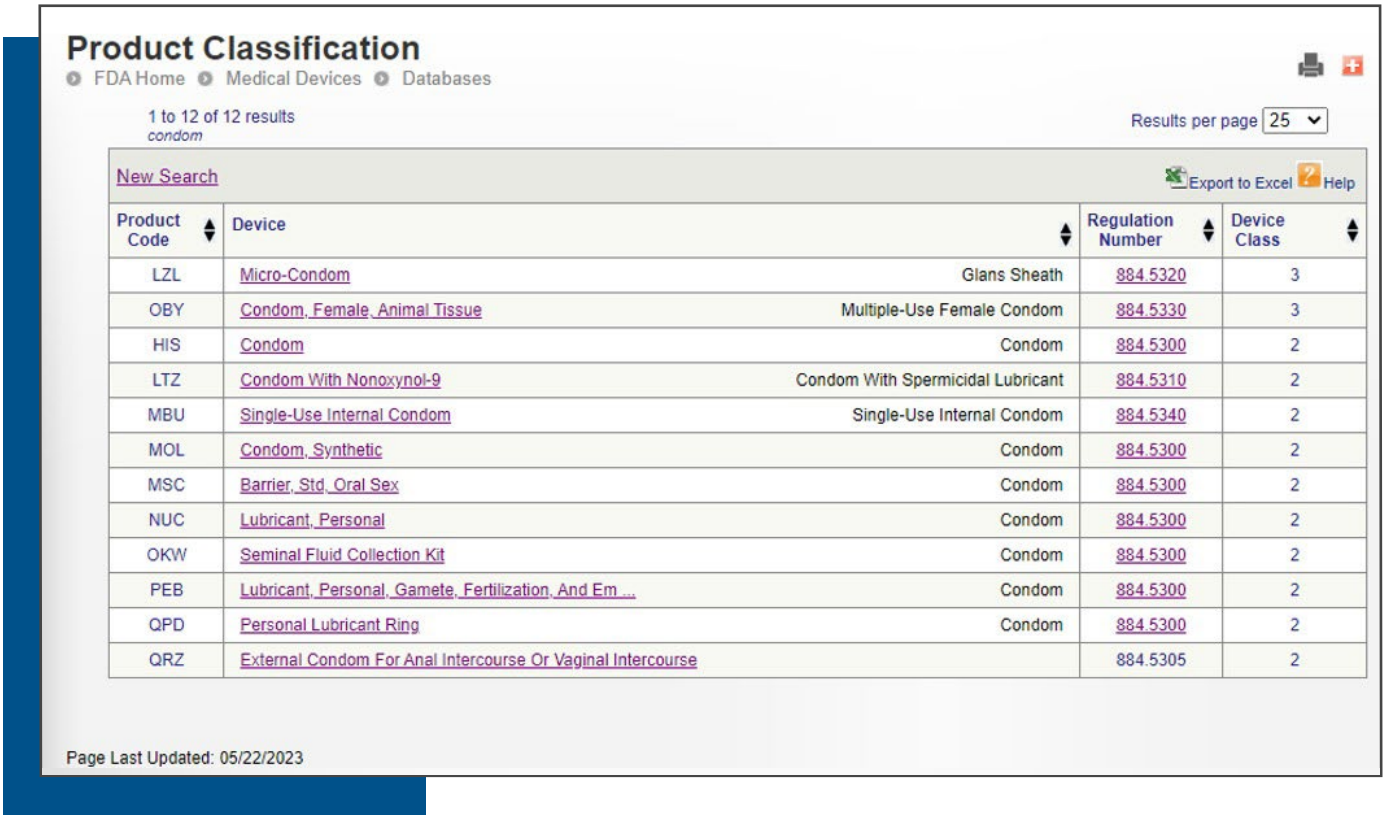


Figure 10 – Product Classification Database Comparison — Quick Search Option (Top) vs. Advanced Search Option (Bottom) for "Condom" – Continued



Product Classification

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1 to 12 of 12 results
condom

Results per page 25

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Product Code	Device		Regulation Number	Device Class
LZL	Micro-Condom	Glans Sheath	884.5320	3
OBY	Condom, Female, Animal Tissue	Multiple-Use Female Condom	884.5330	3
HIS	Condom	Condom	884.5300	2
LTZ	Condom With Nonoxynol-9	Condom With Spermicidal Lubricant	884.5310	2
MBU	Single-Use Internal Condom	Single-Use Internal Condom	884.5340	2
MOL	Condom, Synthetic	Condom	884.5300	2
MSC	Barrier, Std, Oral Sex	Condom	884.5300	2
NUC	Lubricant, Personal	Condom	884.5300	2
OKW	Seminal Fluid Collection Kit	Condom	884.5300	2
PEB	Lubricant, Personal, Gamete, Fertilization, And Em ...	Condom	884.5300	2
QPD	Personal Lubricant Ring	Condom	884.5300	2
QRZ	External Condom For Anal Intercourse Or Vaginal Intercourse		884.5305	2

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In the example above, 11 product codes were extracted from the database using the Quick Search option, and 12 product codes were extracted using the Advanced Search option. Only the Quick Search option retrieved product codes MSC (barrier, STD, oral sex) and OKW (seminal fluid collection kit), while only the advanced search option retrieved product code OBB (kit, conception-assist, home use). All the product codes shown in **Figure 10** in this search example fall under Part 884 Obstetrics/Gynecology, covering the following seven regulation numbers:

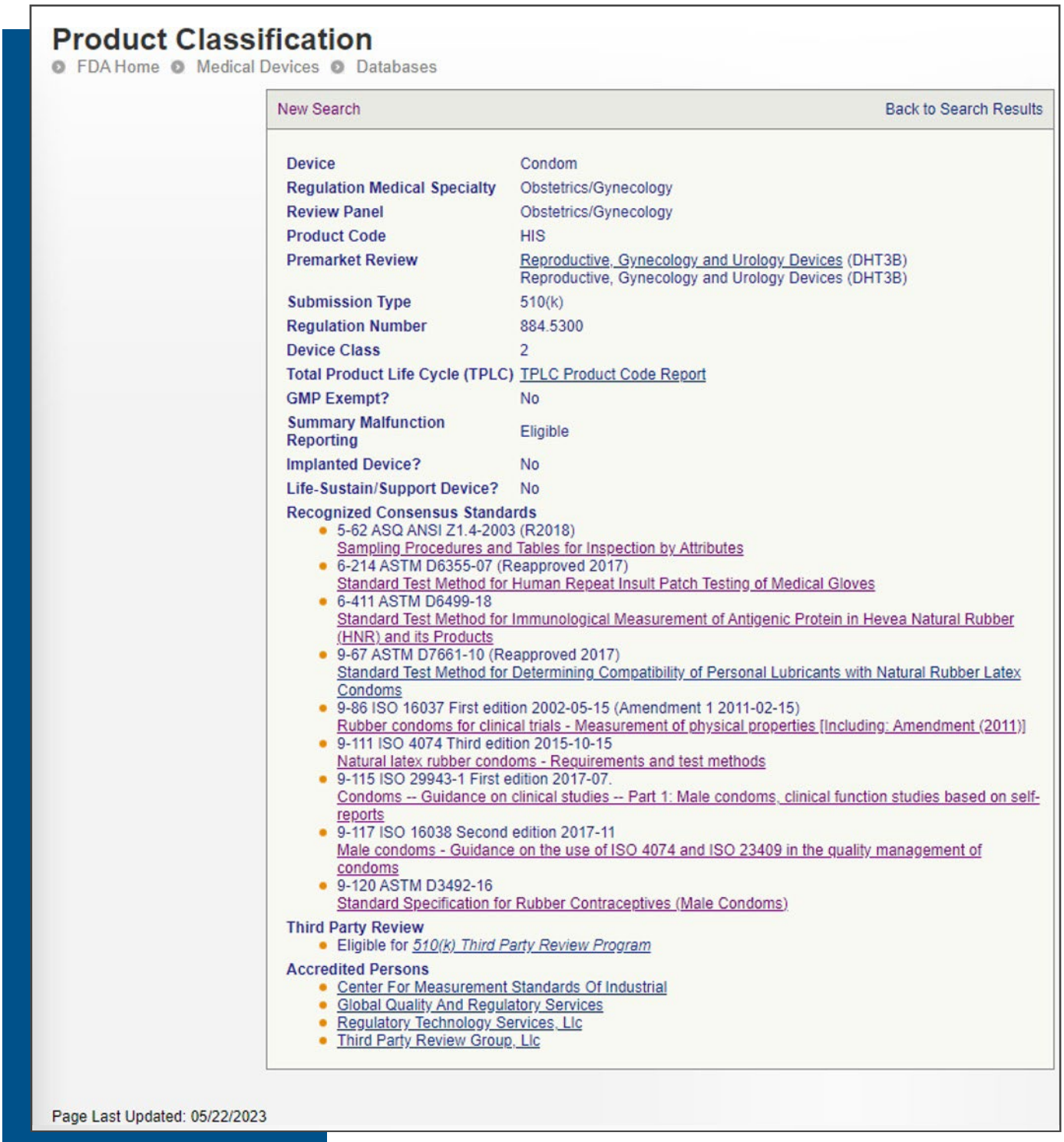
- 884.5250 – Cervical cap
- 884.5300 – Condom
- 884.5305 – The regulation name and description are pending with the FDA as product code QRZ, and the regulation number was established under a De Novo pathway (DEN210034).[2]
- 884.5310 – Condom with spermicidal lubricant
- 884.5320 – Glans sheath
- 884.5330 – Multiple-use female condom
- 884.5340 – Single-use internal condom

From Example 1, we see that all condoms are not the same, based on their product code name and regulation name. This is where a more detailed review of the intended use and technology of a particular type of condom needs to be undertaken to confirm its correct product code and regulation number. Two of the product codes identified in **Figure 10**, OBY (condom, female, animal tissue) and LZL (micro-condom), are Class III devices requiring FDA approval under a PMA submission. All the other product codes identified in this example are Class II devices requiring 510(k) clearance. It is also noted that six of the devices listed above do not appear to even be condoms, based on their product code names and other descriptive information found on their respective product classification pages when compared to product code HIS (condom) and its regulation number, 884.5300. Those devices are:

- Product code MSC (barrier, STD, oral sex)/884.5300
- Product code NUC (lubricant, personal)/884.5300
- Product code OBB (kit, conception-assist, home use)/884.5250
- Product code PEB (lubricant, personal, gamete, fertilization, and embryo-compatible)/884.5300
- Product code QPD (personal lubricant ring)/884.5300
- Product code OKW (seminal fluid collection kit)/884.5300

As product codes NUC and QPD, which are personal lubricants in different forms, share the same regulation as condoms in 884.5300, their product classification pages seen in **Figure 11** have additional descriptive information (i.e., description, physical state, technical method and target area) that differentiates them from a condom because the description of a condom found in 884.5300 makes no reference to any type of lubricant. However, since personal lubricants are often used with condoms, the FDA regulates them under the condom regulation, 884.5300. The same analysis applies to product codes MSC and OKW, which are also regulated in 884.5300.

Figure 11 – Product Classification Pages for Product Codes HIS, NUC and QPD/Regulated in 884.5300



Product Classification

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Device	Condom
Regulation Medical Specialty	Obstetrics/Gynecology
Review Panel	Obstetrics/Gynecology
Product Code	HIS
Premarket Review	Reproductive, Gynecology and Urology Devices (DHT3B) Reproductive, Gynecology and Urology Devices (DHT3B)
Submission Type	510(k)
Regulation Number	884.5300
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	No
Life-Sustain/Support Device?	No

Recognized Consensus Standards

- 5-62 ASQ ANSI Z1.4-2003 (R2018)
  Sampling Procedures and Tables for Inspection by Attributes
- 6-214 ASTM D6355-07 (Reapproved 2017)
  Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves
- 6-411 ASTM D6499-18
  Standard Test Method for Immunological Measurement of Antigenic Protein in Hevea Natural Rubber (HNR) and its Products
- 9-67 ASTM D7661-10 (Reapproved 2017)
  Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms
- 9-86 ISO 16037 First edition 2002-05-15 (Amendment 1 2011-02-15)
  Rubber condoms for clinical trials - Measurement of physical properties [Including: Amendment (2011)]
- 9-111 ISO 4074 Third edition 2015-10-15
  Natural latex rubber condoms - Requirements and test methods
- 9-115 ISO 29943-1 First edition 2017-07.
  Condoms -- Guidance on clinical studies -- Part 1: Male condoms, clinical function studies based on self-reports
- 9-117 ISO 16038 Second edition 2017-11
  Male condoms - Guidance on the use of ISO 4074 and ISO 23409 in the quality management of condoms
- 9-120 ASTM D3492-16
  Standard Specification for Rubber Contraceptives (Male Condoms)

Third Party Review

- Eligible for *510(k) Third Party Review Program*

Accredited Persons

- Center For Measurement Standards Of Industrial
- Global Quality And Regulatory Services
- Regulatory Technology Services, Llc
- Third Party Review Group, Llc

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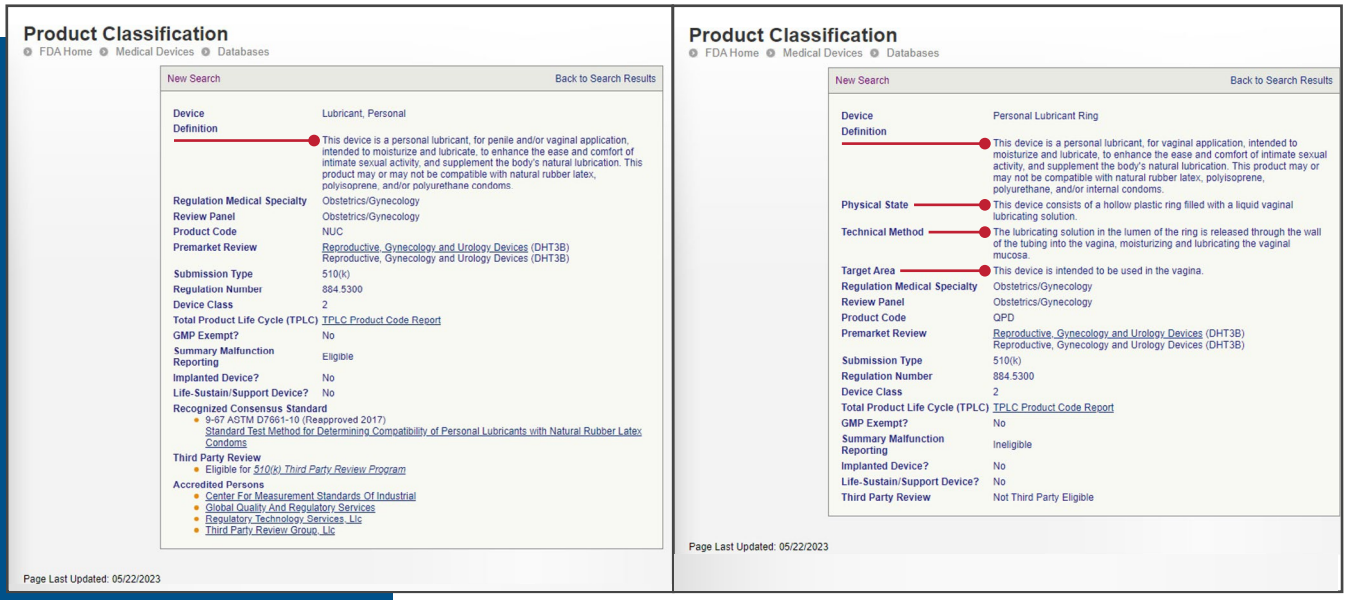
Figure 11 – Product Classification Pages for Product Codes HIS, NUC and QPD/Regulated in 884.5300 – Continued



Product Classification

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Device	Lubricant, Personal
Definition	This device is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. This product may or may not be compatible with natural rubber latex, polyisoprene, and/or polyurethane condoms.
Regulation Medical Specialty	Obstetrics/Gynecology
Review Panel	Obstetrics/Gynecology
Product Code	NUC
Premarket Review	Reproductive, Gynecology and Urology Devices (DHT3B) Reproductive, Gynecology and Urology Devices (DHT3B)
Submission Type	510(k)
Regulation Number	884.5300
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Recognized Consensus Standard	• 9-67 ASTM D7661-10 (Reapproved 2017) Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms
Third Party Review	• Eligible for 510(k) Third Party Review Program
Accredited Persons	• Center For Measurement Standards Of Industrial • Global Quality And Regulatory Services • Regulatory Technology Services, Llc • Third Party Review Group, Llc

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Product Classification

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Device	Personal Lubricant Ring
Definition	This device is a personal lubricant, for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. This product may or may not be compatible with natural rubber latex, polyisoprene, polyurethane, and/or internal condoms.
Physical State	This device consists of a hollow plastic ring filled with a liquid vaginal lubricating solution.
Technical Method	The lubricating solution in the lumen of the ring is released through the wall of the tubing into the vagina, moisturizing and lubricating the vaginal mucosa.
Target Area	This device is intended to be used in the vagina.
Regulation Medical Specialty	Obstetrics/Gynecology
Review Panel	Obstetrics/Gynecology
Product Code	QPD
Premarket Review	Reproductive, Gynecology and Urology Devices (DHT3B) Reproductive, Gynecology and Urology Devices (DHT3B)
Submission Type	510(k)
Regulation Number	884.5300
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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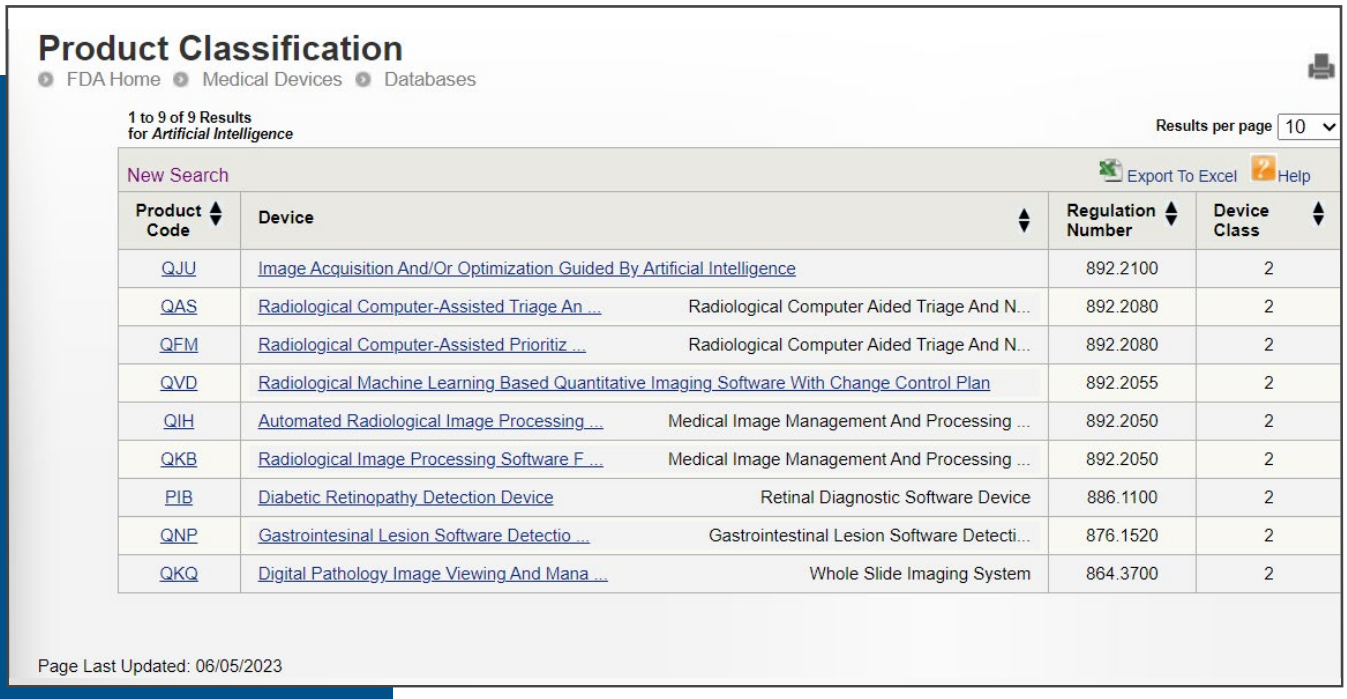
Classification Example 2 – Devices with artificial intelligence

The figure below shows the major differences when using the Quick Search option and Advanced Search option using the words "artificial intelligence."

Figure 12 – Product Classification Database Comparison — Quick View (Top) vs. Advanced View (Bottom) Search Results for "Artificial Intelligence"



Product Classification

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for *Artificial Intelligence*

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Product Code	Device		Regulation Number	Device Class
QJU	Image Acquisition And/Or Optimization Guided By Artificial Intelligence		892.2100	2
QAS	Radiological Computer-Assisted Triage An ...	Radiological Computer Aided Triage And N...	892.2080	2
QFM	Radiological Computer-Assisted Prioritiz ...	Radiological Computer Aided Triage And N...	892.2080	2
QVD	Radiological Machine Learning Based Quantitative Imaging Software With Change Control Plan		892.2055	2
QIH	Automated Radiological Image Processing ...	Medical Image Management And Processing ...	892.2050	2
QKB	Radiological Image Processing Software F ...	Medical Image Management And Processing ...	892.2050	2
PIB	Diabetic Retinopathy Detection Device	Retinal Diagnostic Software Device	886.1100	2
QNP	Gastrointesinal Lesion Software Detectio ...	Gastrointestinal Lesion Software Detecti...	876.1520	2
QKQ	Digital Pathology Image Viewing And Mana ...	Whole Slide Imaging System	864.3700	2

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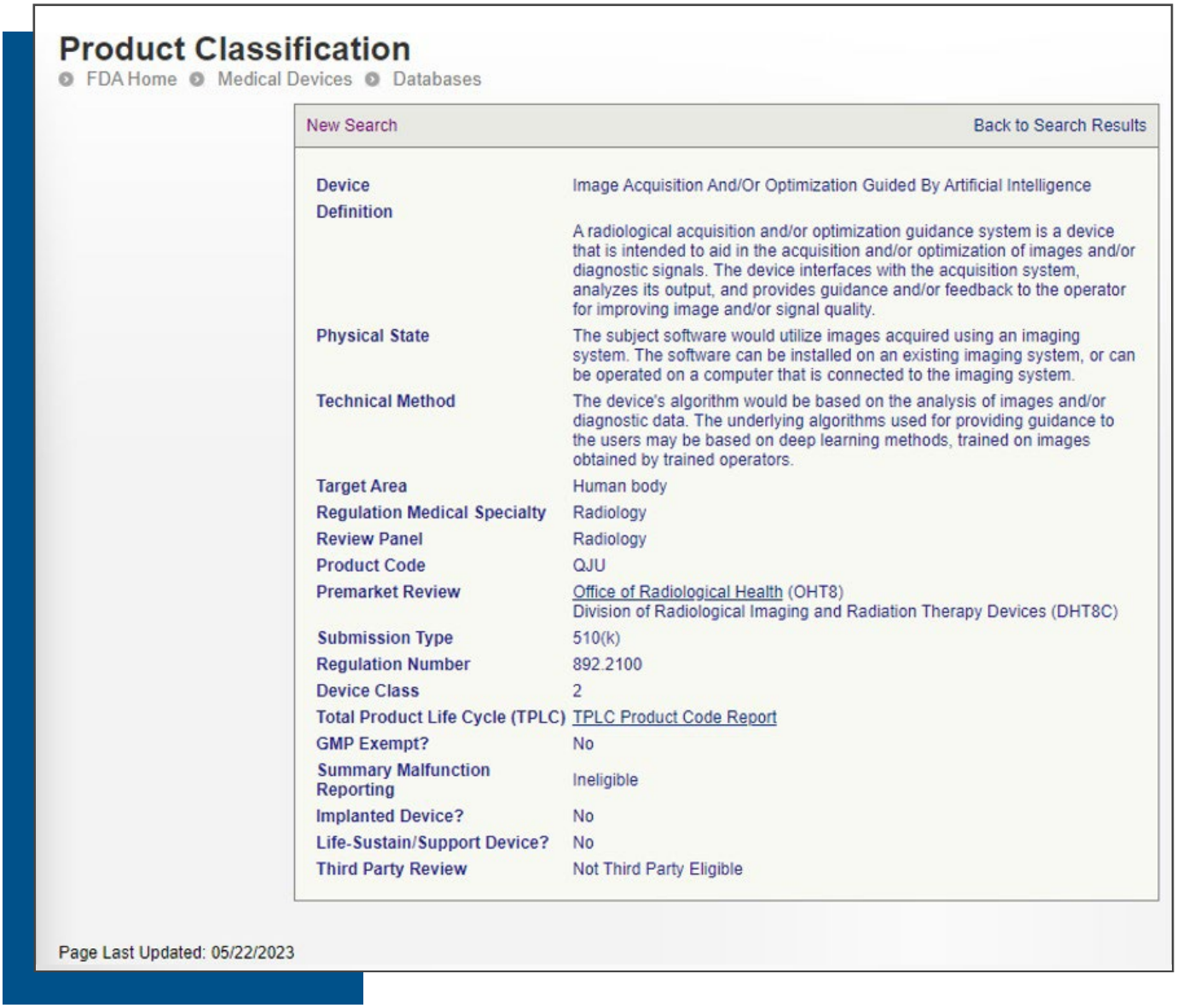
Figure 12 – Product Classification Database Comparison — Quick View (Top) vs. Advanced View (Bottom) Search Results for "Artificial Intelligence" – Continued



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Device	Image Acquisition And/Or Optimization Guided By Artificial Intelligence
Definition	A radiological acquisition and/or optimization guidance system is a device that is intended to aid in the acquisition and/or optimization of images and/or diagnostic signals. The device interfaces with the acquisition system, analyzes its output, and provides guidance and/or feedback to the operator for improving image and/or signal quality.
Physical State	The subject software would utilize images acquired using an imaging system. The software can be installed on an existing imaging system, or can be operated on a computer that is connected to the imaging system.
Technical Method	The device's algorithm would be based on the analysis of images and/or diagnostic data. The underlying algorithms used for providing guidance to the users may be based on deep learning methods, trained on images obtained by trained operators.
Target Area	Human body
Regulation Medical Specialty	Radiology
Review Panel	Radiology
Product Code	QJU
Premarket Review	Office of Radiological Health (OHT8) Division of Radiological Imaging and Radiation Therapy Devices (DHT8C)
Submission Type	510(k)
Regulation Number	892.2100
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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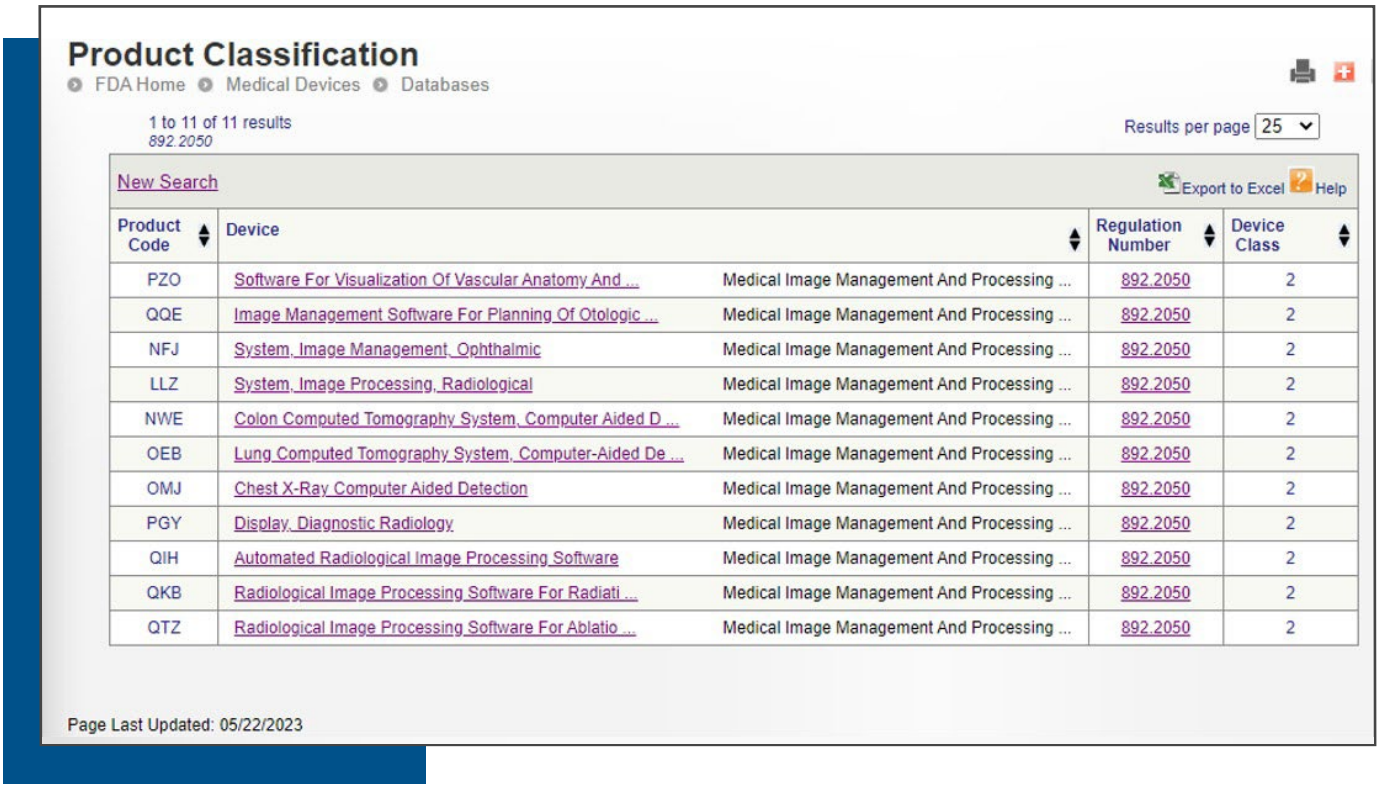
In the example above, nine product codes were extracted from the database using the Quick Search option and just one product code (QJU) was extracted using the Advanced Search option. The product code QJU was also extracted using the Quick Search option. The regulation numbers were arranged in the first screenshot above to group the product codes by review panel. The first six product codes fall under Part 892 Radiology, covering the following four regulation numbers:

- 892.2100 – The regulation name and description are pending with the FDA as product code QJU (image acquisition and/or optimization guided by artificial intelligence), and the regulation number were established under a De Novo pathway (DEN190040).[3] There are no other product codes in this regulation.
- 892.2080 – Radiological computer-aided triage and notification software: Product code QAS (radiological computer-assisted triage and notification software) and the regulation number were established under a De Novo pathway (DEN170073).[4] Product code QFM (radiological computer-assisted prioritization software for lesions) was added to the regulation with a different name and technical method. There are no other product codes in this regulation.
- 892.2055 – The regulation name and description are pending with the FDA as product code QVD (radiological machine learning-based quantitative imaging software with change control plan), and the regulation number were established under a De Novo pathway (DEN220063).[5] There are no other product codes in this regulation.

- 892.2050 – Medical image management and processing system: Product codes QIH (automated radiological image processing software) and QKB (radiological image processing software for radiation therapy) were added to the regulation, each with a different device name than what appears in the regulation and with added definitions and technical methods on their respective product classification pages that do not appear in the original regulation. There are 11 product codes in this regulation, as seen in **Figure 13**. Artificial intelligence is not referenced in the regulation or in the names for product codes QIH and QKB. However, artificial intelligence is mentioned in the definition and technical method for both of these product codes on their respective product classification pages. The intended use of these two devices is reflected in their respective definitions.

Figure 13 – Product Codes in 892.2050



Product Classification

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892.2050

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Product Code	Device		Regulation Number	Device Class
PZO	Software For Visualization Of Vascular Anatomy And ...	Medical Image Management And Processing ...	892.2050	2
QQE	Image Management Software For Planning Of Otologic ...	Medical Image Management And Processing ...	892.2050	2
NFJ	System, Image Management, Ophthalmic	Medical Image Management And Processing ...	892.2050	2
LLZ	System, Image Processing, Radiological	Medical Image Management And Processing ...	892.2050	2
NWE	Colon Computed Tomography System, Computer Aided D ...	Medical Image Management And Processing ...	892.2050	2
OEB	Lung Computed Tomography System, Computer-Aided De ...	Medical Image Management And Processing ...	892.2050	2
OMJ	Chest X-Ray Computer Aided Detection	Medical Image Management And Processing ...	892.2050	2
PGY	Display, Diagnostic Radiology	Medical Image Management And Processing ...	892.2050	2
QIH	Automated Radiological Image Processing Software	Medical Image Management And Processing ...	892.2050	2
QKB	Radiological Image Processing Software For Radiati ...	Medical Image Management And Processing ...	892.2050	2
QTZ	Radiological Image Processing Software For Ablatio ...	Medical Image Management And Processing ...	892.2050	2

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The last three product codes in the table from **Figure 12** fall under Part 886 Ophthalmic, Part 876 Gastroenterology/Urology and Part 864 Pathology, covering the following three regulations:

- 886.1100 – Retinal diagnostic software device: Product code PIB (diabetic retinopathy detection device) and the regulation were established under a De Novo pathway (DEN 180001).[6] Artificial intelligence is referenced in the technical method for this device on its product classification page. The intended use of this device is reflected in its definition. There are no other product codes in this regulation.
- 876.1520 – Gastrointestinal lesion software detection system: Product code QNP (gastrointestinal lesion software detection system) and the regulation were established under a De Novo pathway (DEN200055).[7] Artificial intelligence is referenced in the technical method for this device on its product classification page. The intended use of this device is reflected in its definition. There are no other product codes in this regulation.
- 864.3700 – Whole slide imaging system: Product code QKQ (digital pathology image viewing and management software) was added to the regulation with a different device name, definition, physical state, technical method and target area than what appears for product code PSY (whole slide imaging system) that established this regulation under a De Novo pathway (DEN160056).[8] Artificial intelligence is referenced in the technical method for product code QKQ on its product classification page. The intended use of this device is reflected in its definition. There is one other product code, PZZ (digital pathology display), in this regulation.

From Example 2, we see that there are several devices that all have some form of artificial intelligence with different intended uses and, as such, have been classified by the FDA under nine different products codes covering seven different regulation numbers and four review panels (Radiology, Ophthalmic, Gastroenterology/Urology and Pathology) as Class II devices; five of the product codes and regulation numbers have been established under De Novo pathways.

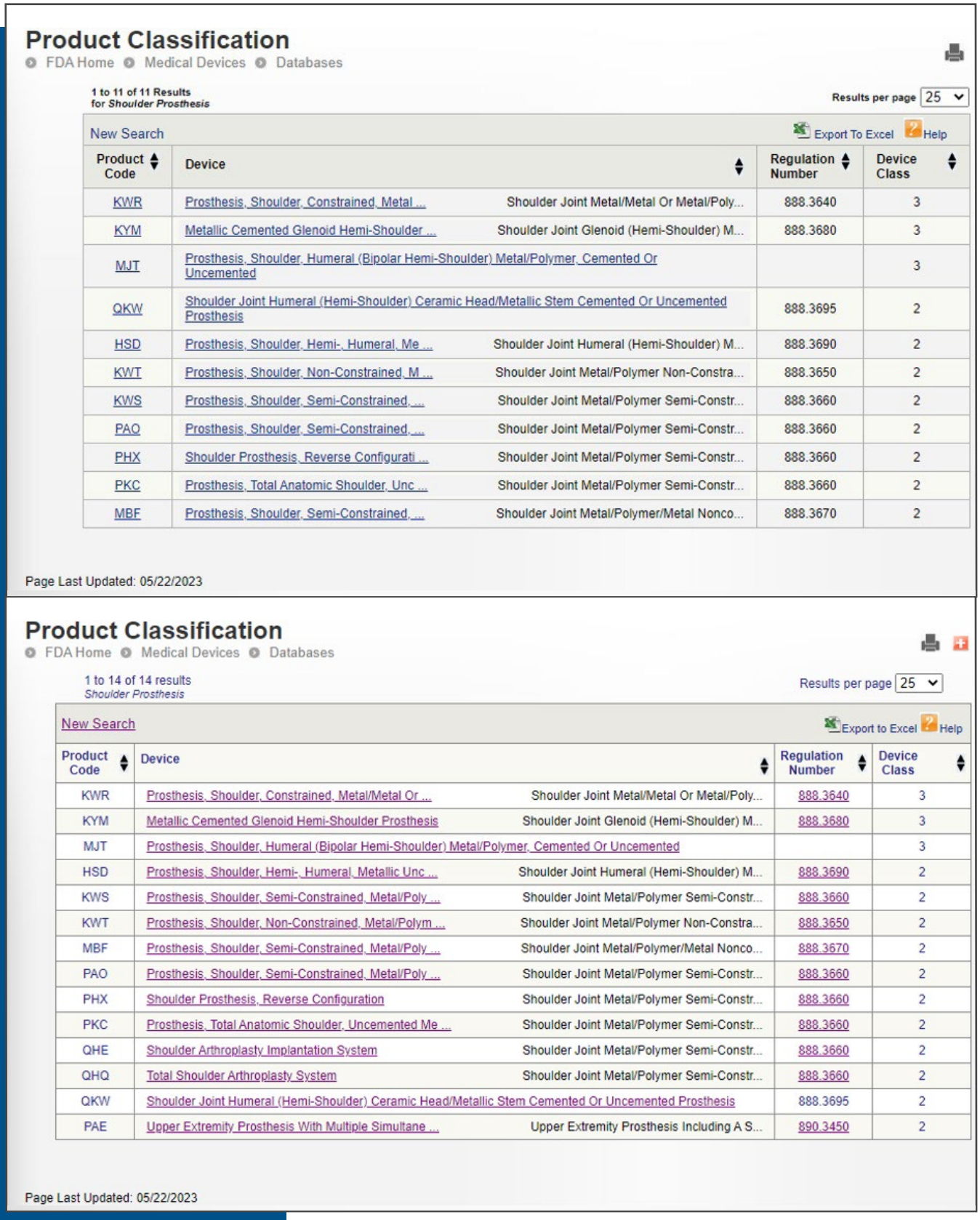
It should be noted that only the product code and regulation are searched, and not the individual devices; not all product codes and regulations reference a specific technology. Therefore, while this is a good beginning point for researching devices with artificial intelligence, it should not be the only search, and there may be other devices with artificial intelligence that were not found in the search.

Classification Example 3 – Orthopedic implants — shoulder prosthesis

Few medical devices at the Center for Device and Radiological Health (CDRH) are more complicated to correctly classify than prosthetic hip, knee and shoulder systems because of their different intended uses, indications for use, design features and the components/materials used to make them. These complications can result in some device systems requiring PMA submissions while other device systems require 510(k) submissions. For this classification example, prosthetic shoulder systems were selected because there are fewer product codes to describe these device systems than there are for prosthetic hip and knee systems.

The figure below shows the subtle differences when using the Quick Search option and Advanced Search option using the words “shoulder prosthesis.”

Figure 14 – Product Classification Database Comparison — Quick View (Top) vs. Advanced View (Bottom) Search Results for "Shoulder Prosthesis"



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for *Shoulder Prosthesis*

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Product Code	Device		Regulation Number	Device Class
KWR	Prosthesis, Shoulder, Constrained, Metal ...	Shoulder Joint Metal/Metal Or Metal/Poly...	888.3640	3
KYM	Metallic Cemented Glenoid Hemi-Shoulder ...	Shoulder Joint Glenoid (Hemi-Shoulder) M...	888.3680	3
MJT	Prosthesis, Shoulder, Humeral (Bipolar Hemi-Shoulder) Metal/Polymer, Cemented Or Uncemented			3
QKW	Shoulder Joint Humeral (Hemi-Shoulder) Ceramic Head/Metallic Stem Cemented Or Uncemented Prosthesis		888.3695	2
HSD	Prosthesis, Shoulder, Hemi-, Humeral, Me ...	Shoulder Joint Humeral (Hemi-Shoulder) M...	888.3690	2
KWT	Prosthesis, Shoulder, Non-Constrained, M ...	Shoulder Joint Metal/Polymer Non-Constra...	888.3650	2
KWS	Prosthesis, Shoulder, Semi-Constrained, ...	Shoulder Joint Metal/Polymer Semi-Constr...	888.3660	2
PAO	Prosthesis, Shoulder, Semi-Constrained, ...	Shoulder Joint Metal/Polymer Semi-Constr...	888.3660	2
PHX	Shoulder Prosthesis, Reverse Configurati ...	Shoulder Joint Metal/Polymer Semi-Constr...	888.3660	2
PKC	Prosthesis, Total Anatomic Shoulder, Unc ...	Shoulder Joint Metal/Polymer Semi-Constr...	888.3660	2
MBF	Prosthesis, Shoulder, Semi-Constrained, ...	Shoulder Joint Metal/Polymer/Metal Nonco...	888.3670	2

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Shoulder Prosthesis

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Product Code	Device		Regulation Number	Device Class
KWR	Prosthesis, Shoulder, Constrained, Metal/Metal Or ...	Shoulder Joint Metal/Metal Or Metal/Poly...	888.3640	3
KYM	Metallic Cemented Glenoid Hemi-Shoulder Prosthesis	Shoulder Joint Glenoid (Hemi-Shoulder) M...	888.3680	3
MJT	Prosthesis, Shoulder, Humeral (Bipolar Hemi-Shoulder) Metal/Polymer, Cemented Or Uncemented			3
HSD	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Unc ...	Shoulder Joint Humeral (Hemi-Shoulder) M...	888.3690	2
KWS	Prosthesis, Shoulder, Semi-Constrained, Metal/Poly ...	Shoulder Joint Metal/Polymer Semi-Constr...	888.3660	2
KWT	Prosthesis, Shoulder, Non-Constrained, Metal/Polym ...	Shoulder Joint Metal/Polymer Non-Constra...	888.3650	2
MBF	Prosthesis, Shoulder, Semi-Constrained, Metal/Poly ...	Shoulder Joint Metal/Polymer/Metal Nonco...	888.3670	2
PAO	Prosthesis, Shoulder, Semi-Constrained, Metal/Poly ...	Shoulder Joint Metal/Polymer Semi-Constr...	888.3660	2
PHX	Shoulder Prosthesis, Reverse Configuration	Shoulder Joint Metal/Polymer Semi-Constr...	888.3660	2
PKC	Prosthesis, Total Anatomic Shoulder, Uncemented Me ...	Shoulder Joint Metal/Polymer Semi-Constr...	888.3660	2
QHE	Shoulder Arthroplasty Implantation System	Shoulder Joint Metal/Polymer Semi-Constr...	888.3660	2
QHQ	Total Shoulder Arthroplasty System	Shoulder Joint Metal/Polymer Semi-Constr...	888.3660	2
QKW	Shoulder Joint Humeral (Hemi-Shoulder) Ceramic Head/Metallic Stem Cemented Or Uncemented Prosthesis		888.3695	2
PAE	Upper Extremity Prosthesis With Multiple Simultane ...	Upper Extremity Prosthesis Including A S...	890.3450	2

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In the example above, we see that 11 product codes were extracted from the database using the Quick Search option, and 14 product codes were extracted using the Advanced Search option. Product codes QHE, QHQ and PAE were not extracted using the Quick Search option. In looking further at all the product codes that were extracted using the advanced search option in the second screenshot above, only product code PAE falls under Part 890 Physical Medicine — not Part 888 Orthopedic, the panel that reviews implantable orthopedic devices.

The other 13 product codes shown in **Figure 14** in this search example cover the following seven regulation numbers, while product code MJT (prosthesis, shoulder, humeral (bipolar hemi-shoulder) metal/polymer, cemented or uncemented) is a Class III device that has not been assigned a regulation number, and its current submission type described on its product classification page requires communication with the Office of Device Evaluation to confirm its submission type.

- 888.3640 – Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis: Product code KWR (prosthesis, shoulder, constrained, metal/metal or metal/polymer cemented) has the same name as the regulation and is a Class III device that requires FDA approval under a PMA submission. There are no other product codes in this regulation.
- 888.3650 – Shoulder joint metal/polymer non-constrained cemented prosthesis: Product code KWT (prosthesis, shoulder, non-constrained, metal/polymer cemented) has the same name as the regulation and is a Class II device that requires FDA clearance under a 510(k) submission. There are no other product codes in this regulation.
- 888.3660 – Shoulder joint metal/polymer semi-constrained cemented prosthesis: Product code KWS (prosthesis, shoulder, non-constrained, metal/polymer cemented) has a different name than the regulation and is a Class II device that requires FDA clearance under a 510(k) submission. There are five other product codes in this regulation — PAO (prosthesis, shoulder, semi-constrained, metal/polymer with additive, cemented), PHX (prosthesis, shoulder, semi-constrained, metal/polymer with additive, cemented), PKC (prosthesis, total anatomic shoulder, uncemented metaphyseal humeral stem with no diaphyseal incursion, semi-constrained), QHE (shoulder arthroplasty implantation system) and QHQ (total shoulder arthroplasty system) — and each has a different name than the regulation name. They also have additional descriptive information (definition, physical state and technical method) on their respective product classification pages.
- 888.3670 – Shoulder joint metal/polymer/metal non-constrained or semi-constrained porous-coated uncemented prosthesis: Product code MBF (prosthesis, shoulder, semi-constrained, metal/polymer, uncemented) has a similar name as the regulation and is a Class II device that requires FDA clearance under a 510(k) submission. There are no other product codes in this regulation.
- 888.3680 – Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis: Product code KYM (metallic cemented glenoid hemi-shoulder prosthesis) has the same name as the regulation and is a Class III device that requires FDA approval under a PMA submission. There are no other product codes in this regulation.
- 888.3690 – Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis: Product code HSD (prosthesis, shoulder, hemi-, humeral, metallic uncemented) has the same name as the regulation and is a Class II device that requires FDA clearance under a 510(k) submission. There are no other product codes in this regulation.
- 888.3695 – The regulation name and description are pending as product code QKW (shoulder joint humeral (hemi-shoulder) ceramic head/metallic stem cemented or uncemented prosthesis) were established under a De Novo pathway (DEN220012).[9] There are no other product codes in this regulation.

From Example 3, we see that there are 13 product codes for the distinct types of prosthetic shoulder systems covering seven different regulation numbers that are all reviewed by the Orthopedic device panel as either Class II or Class III devices subject to 510(k) and PMA submissions, respectively. When trying to correctly classify prosthetic shoulder systems, as well as hip and knee systems, it is crucial to fully understand the overall design of these complicated joint systems as well as the main components and materials used to make them. Therefore, the different regulation number descriptions as well as the product classification pages need to be reviewed and understood, especially when the product classification page has additional descriptive information related to the device name, definition, physical state, technical method and target area (which some product codes do not have), as this additional information is not always found in regulation number descriptions.

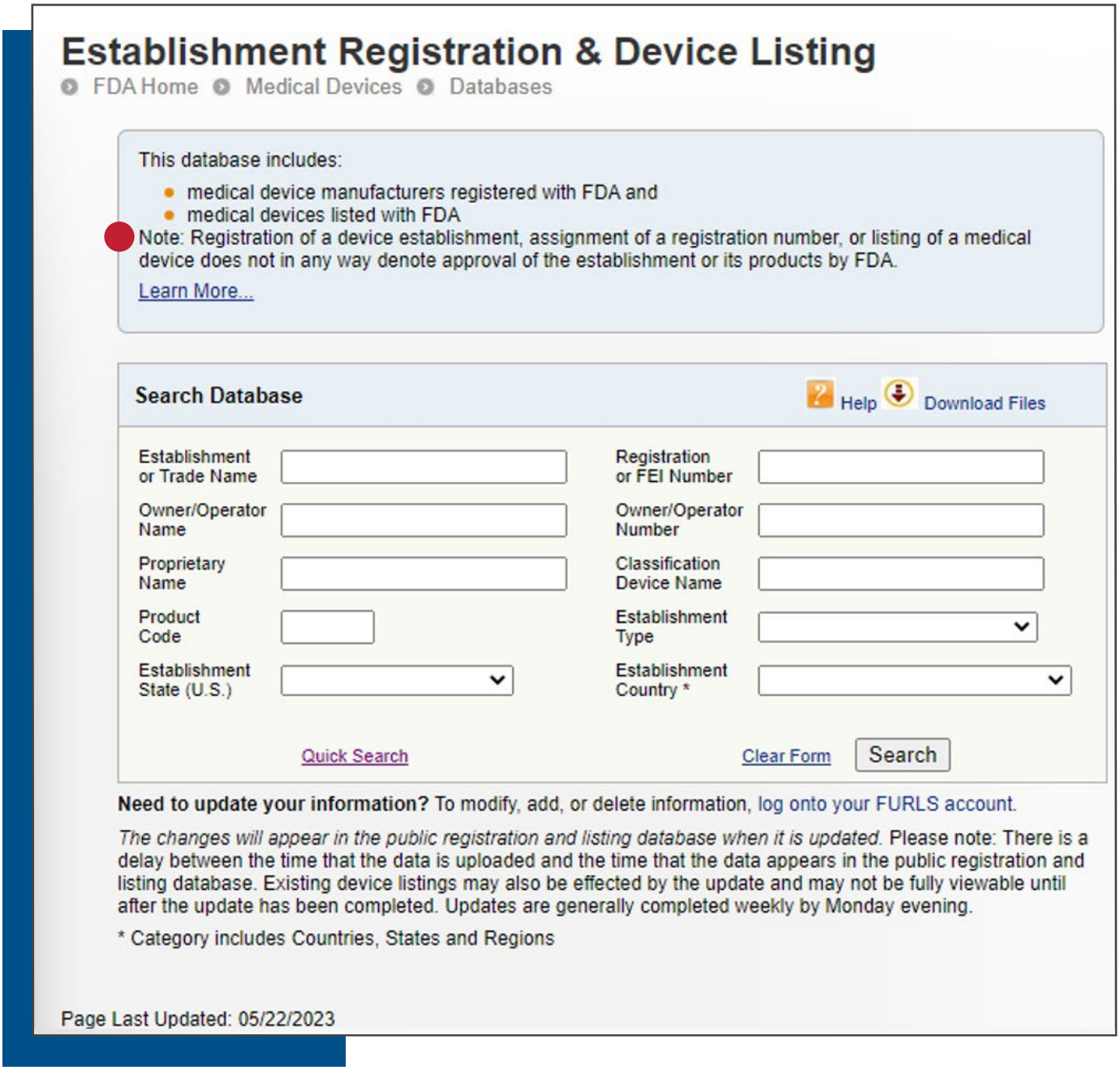
Using other FDA databases

Several other FDA databases within the CDRH that were identified above can also be used to classify or further confirm the classification of your device. These databases are best used if you know of another device that is the same as or like your device in terms of its intended use and technology and that has been listed, cleared and/or approved by the FDA. In this section, we will focus on the FDA's Registration and Listing (R&L) database and their 510(k) database. Using the FDA's De Novo, PMA and HDE databases is similar to using the 510(k) database.

Classification Example 4 – Using the FDA R&L database to confirm classification

The FDA's R&L database, as seen in **Figure 15**, is best used when you have a high degree of confidence that your device is the same as or like another legally marketed device in the U.S. with respect to its intended use and technology. It is the manufacturer's responsibility to ensure their device has been correctly classified and listed with the FDA, as seen below.

Figure 15 – FDA Establishment R&L Database

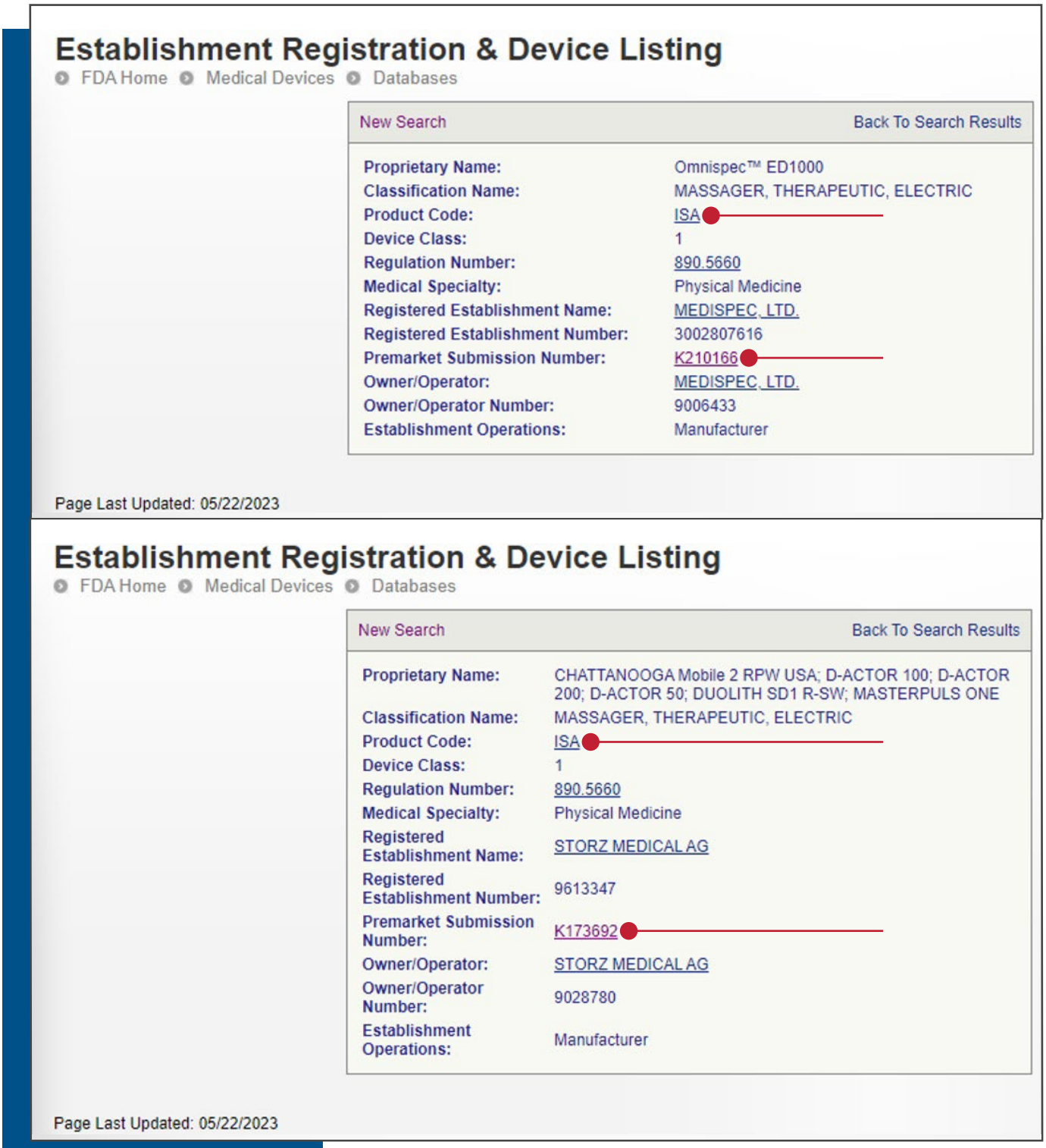


In this example, a new device company wants to manufacture and market hand-held electric massagers in the U.S. and sell them under their own brand name for relief of minor muscle aches and pains to a targeted area of the body. The company has identified product code ISA (massager, therapeutic, electric) in the product classification database as the likely product code, which is a Class I 510(k)-exempt device under 890.5660. To confirm the device classification, the company conducts a search using the FDA's R&L database under product code ISA, which lists 100 different establishment types — e.g., manufacturers, contract manufacturers, specification developers, etc. — registered with the FDA selling electric massagers listed under product code ISA.

In looking closer at the R&L pages for several different establishments, the new company noticed that two companies show their therapeutic electric massagers as also having been cleared by the FDA under two 510(k)s (K210166 and K173692), as seen in **Figure 16**. Upon further review of the two 510(k) summary documents in the 510(k) database, they found that these two electric massagers had broader intended use claims beyond relief of minor muscle aches and pains, including temporary increase in local blood circulation and activation of connective tissue, as well as incorporating more advanced technology than what is typically found in a hand-held electric massager.

Specifically, the device cleared under K210166 uses an electro-hydraulic method of creating shock waves to achieve its intended principles of operation, while the device cleared under K173692 uses pressurized air pulses to achieve its intended principles of operation. These technical characteristics are different than traditional electromechanically induced vibrations produced by the new company's device. Based on this review, the new company concluded that a 510(k) did not need to be submitted to the FDA for their device as the limitations to 510(k) exemption as described in parts (a) and (b) of 890.9 did not apply to the intended use and technology of their therapeutic electric massager.

Figure 16 – FDA Establishment R&L Pages for Two ISA Devices (K210166 and K173692)



Establishment Registration & Device Listing

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Proprietary Name:	Omnispec™ ED1000
Classification Name:	MASSAGER, THERAPEUTIC, ELECTRIC
Product Code:	ISA
Device Class:	1
Regulation Number:	890.5660
Medical Specialty:	Physical Medicine
Registered Establishment Name:	MEDISPEC, LTD.
Registered Establishment Number:	3002807616
Premarket Submission Number:	K210166
Owner/Operator:	MEDISPEC, LTD.
Owner/Operator Number:	9006433
Establishment Operations:	Manufacturer

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Proprietary Name:	CHATTANOOGA Mobile 2 RPW USA; D-ACTOR 100; D-ACTOR 200; D-ACTOR 50; DUOLITH SD1 R-SW; MASTERPULS ONE
Classification Name:	MASSAGER, THERAPEUTIC, ELECTRIC
Product Code:	ISA
Device Class:	1
Regulation Number:	890.5660
Medical Specialty:	Physical Medicine
Registered Establishment Name:	STORZ MEDICAL AG
Registered Establishment Number:	9613347
Premarket Submission Number:	K173692
Owner/Operator:	STORZ MEDICAL AG
Owner/Operator Number:	9028780
Establishment Operations:	Manufacturer

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Classification Example 5 – Using the FDA 510(k) database

The FDA's 510(k) database is best used when you have a high degree of confidence that your device is the same as or like another legally marketed device in the U.S. with respect to its intended use and technology. However, in this example, there are some differences in the technology used in the new company's device when compared to most predicate devices under the same product code, so the manufacturer wants to see if they can narrow down their search effort to confirm whether they can still submit a 510(k) because of the difference in technology in their device, as opposed to having to submit a De Novo.

In this example, the manufacturer produces dental abutments (product code NHA) that are used with dental implants (product code DZE). However, instead of making their dental abutments out of titanium or ceramic, which are the materials used to make most dental abutments, they make them out of the polymer, ployetheretherketone (PEEK).

Knowing that there are more than 500 dental abutments cleared by the FDA, as shown in the 510(k) database when searching using product code NHA, the manufacturer did not want to waste a lot of time looking through dozens of 510(k) summary documents to try to locate a dental abutment made of PEEK that could be used as a predicate device in a future 510(k) submission.

Setting up the predicate device search, the manufacturer used product code NHA, entered the word "PEEK" in the device name field and selected the word "Dental" from the drop-down menu for the device review panel, as seen in **Figure 17**. This search produced five possible predicate devices, seen in **Figure 18**, where the word "PEEK" was found in the trade of the device that was submitted to the FDA. It is possible that other dental abutments have been cleared that are made from PEEK, but if "PEEK" does not appear in the trade name of the device, it is harder to locate such a predicate device without having to look through many 510(k) summary documents.

Figure 17 – FDA 510(k) Database

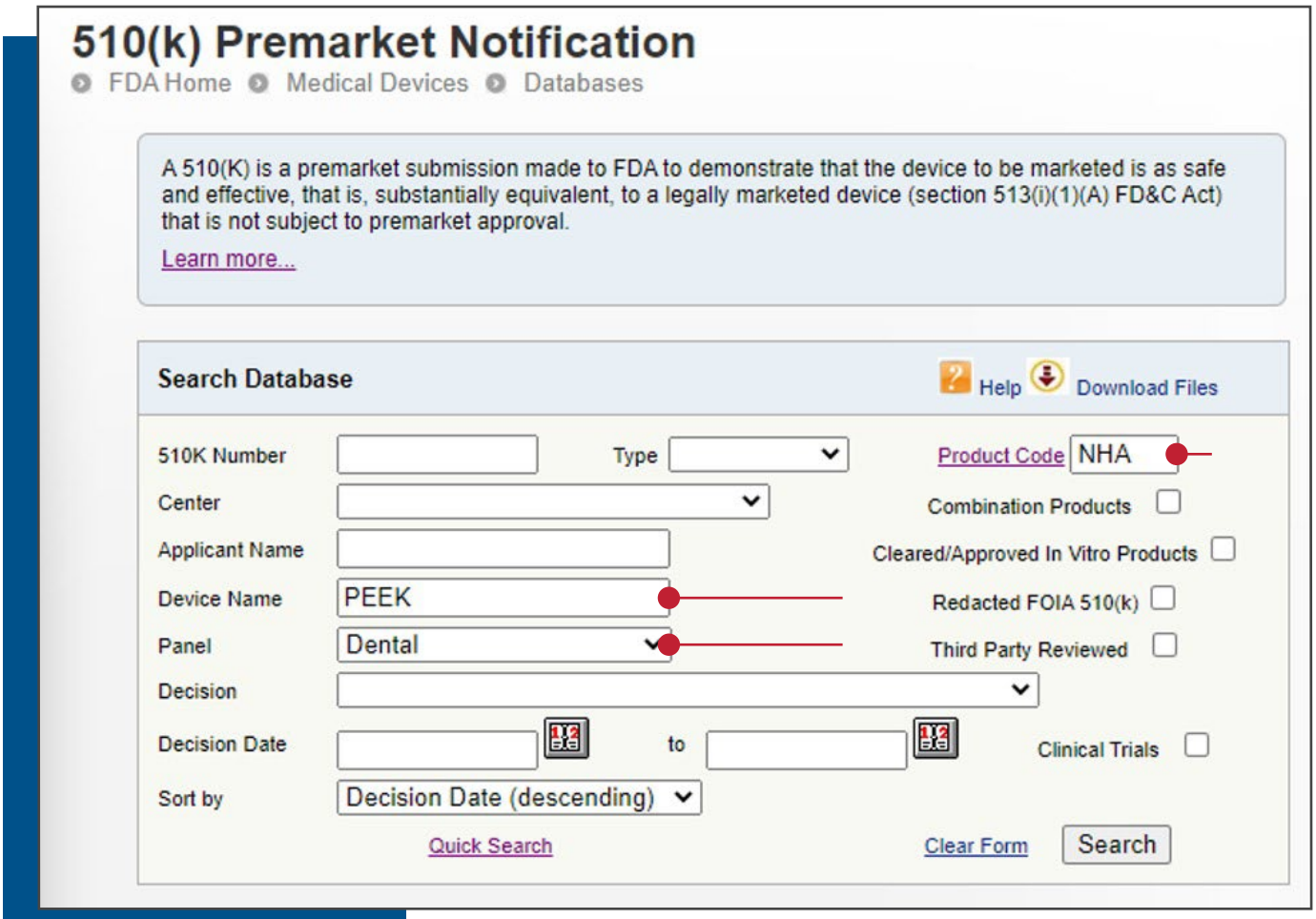
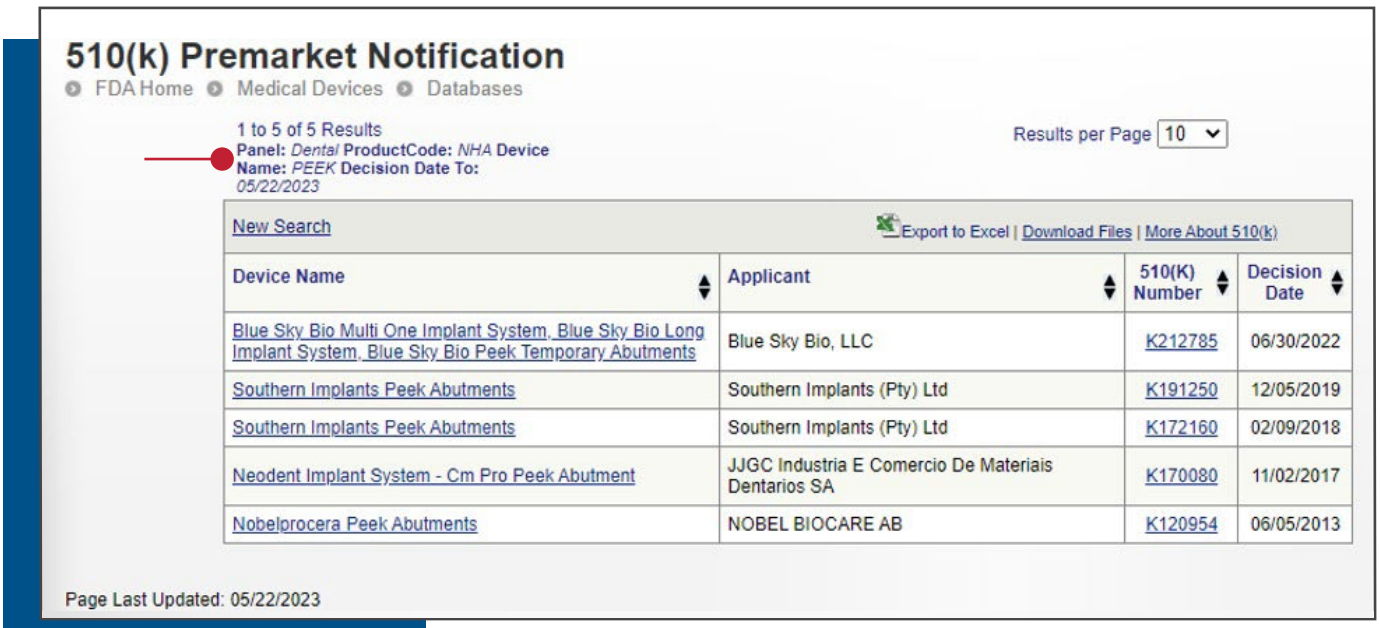


Figure 18 – FDA 510(k) Database Search Results Using "NHA," "PEEK" and "Dental"



Some helpful tips for classifying your device

Locating all product codes in a regulation number

As we have seen in some of the examples above, there can often be 10 or more product codes in the same regulation, and you want to make sure you have selected the correct product code for your device. If you are not sure about the product code of your medical device but are certain of the regulation number that your device falls under based on its intended use and technological characteristics, and assuming that a regulation number has been established by the FDA for your device, insert the regulation number in the regulation number field on the product classification page and all of the product codes in that regulation will be extracted, as seen in **Figure 19** using CFR 880.5725 Infusion Pump. In this example, 17 product codes are extracted for "infusion pump," as seen in **Figure 20**.

Figure 19 – Product Classification Database Using Regulation Number 880.5725

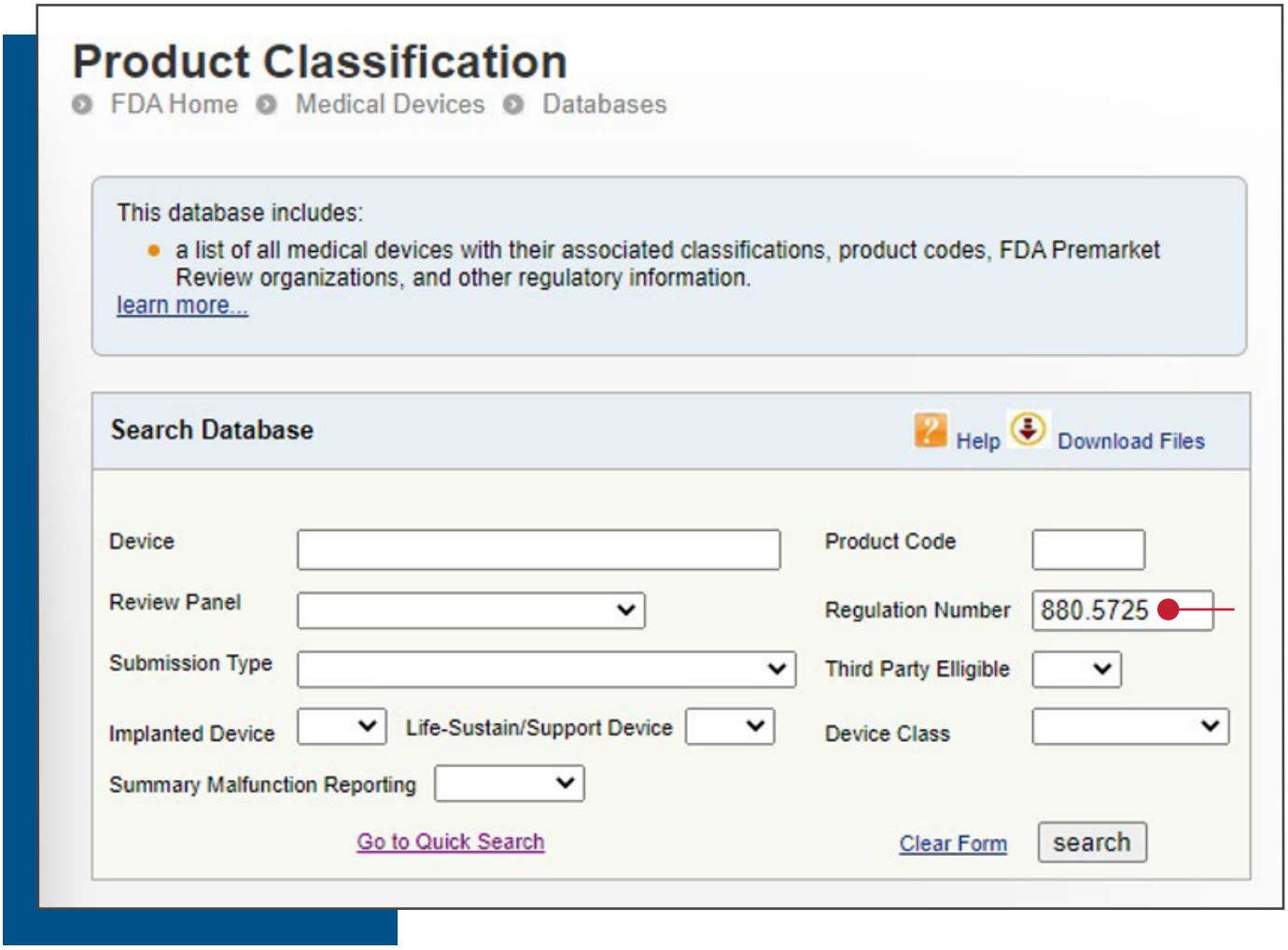
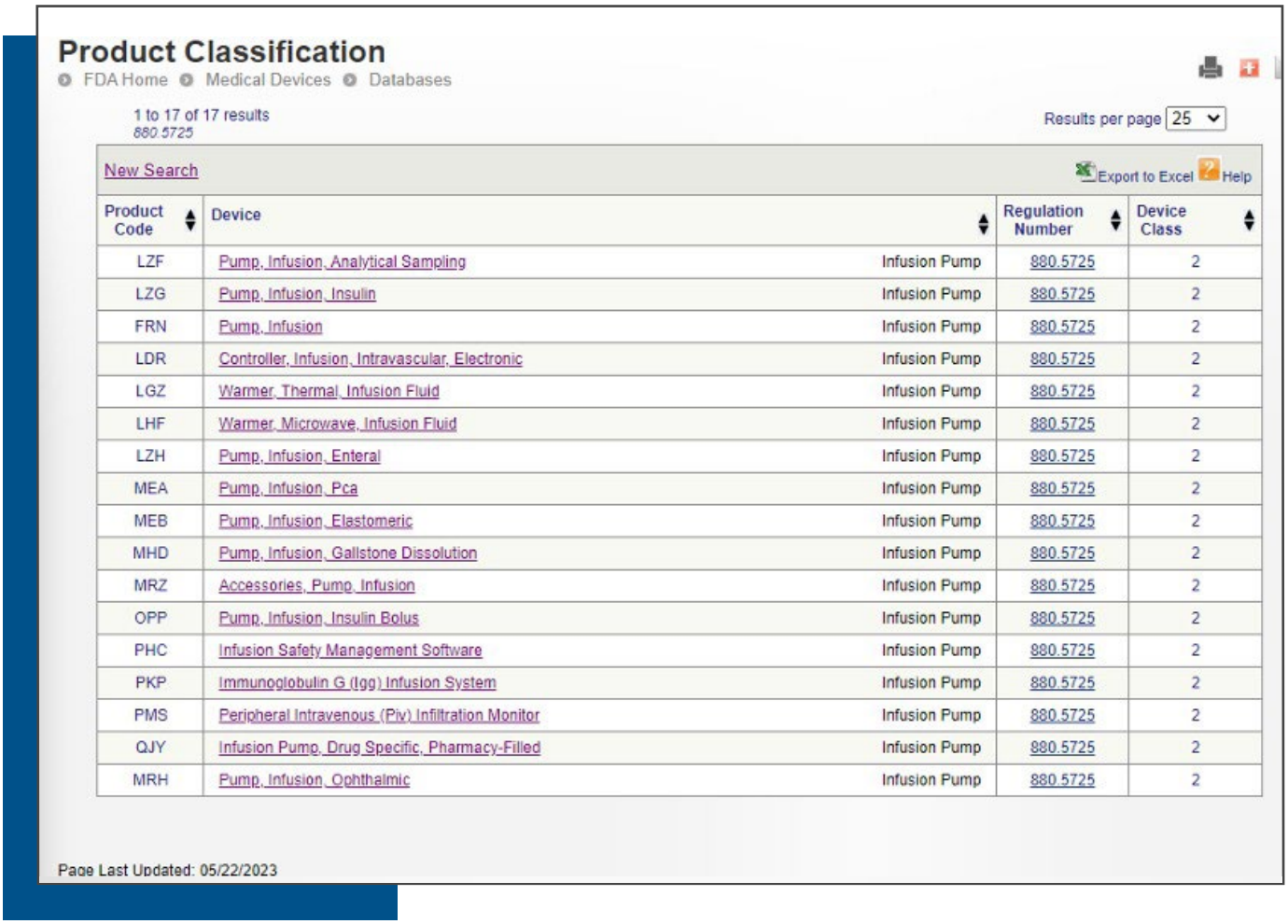


Figure 20 – Product Classification Database Results Using Regulation Number 880.5725



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880.5725

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Product Code	Device		Regulation Number	Device Class
LZF	Pump, Infusion, Analytical Sampling	Infusion Pump	880.5725	2
LZG	Pump, Infusion, Insulin	Infusion Pump	880.5725	2
FRN	Pump, Infusion	Infusion Pump	880.5725	2
LDR	Controller, Infusion, Intravascular, Electronic	Infusion Pump	880.5725	2
LGZ	Warmer, Thermal, Infusion Fluid	Infusion Pump	880.5725	2
LHF	Warmer, Microwave, Infusion Fluid	Infusion Pump	880.5725	2
LZH	Pump, Infusion, Enteral	Infusion Pump	880.5725	2
MEA	Pump, Infusion, Pca	Infusion Pump	880.5725	2
MEB	Pump, Infusion, Elastomeric	Infusion Pump	880.5725	2
MHD	Pump, Infusion, Gallstone Dissolution	Infusion Pump	880.5725	2
MRZ	Accessories, Pump, Infusion	Infusion Pump	880.5725	2
OPP	Pump, Infusion, Insulin Bolus	Infusion Pump	880.5725	2
PHC	Infusion Safety Management Software	Infusion Pump	880.5725	2
PKP	Immunoglobulin G (Igg) Infusion System	Infusion Pump	880.5725	2
PMS	Peripheral Intravenous (Piv) Infiltration Monitor	Infusion Pump	880.5725	2
QJY	Infusion Pump, Drug Specific, Pharmacy-Filled	Infusion Pump	880.5725	2
MRH	Pump, Infusion, Ophthalmic	Infusion Pump	880.5725	2

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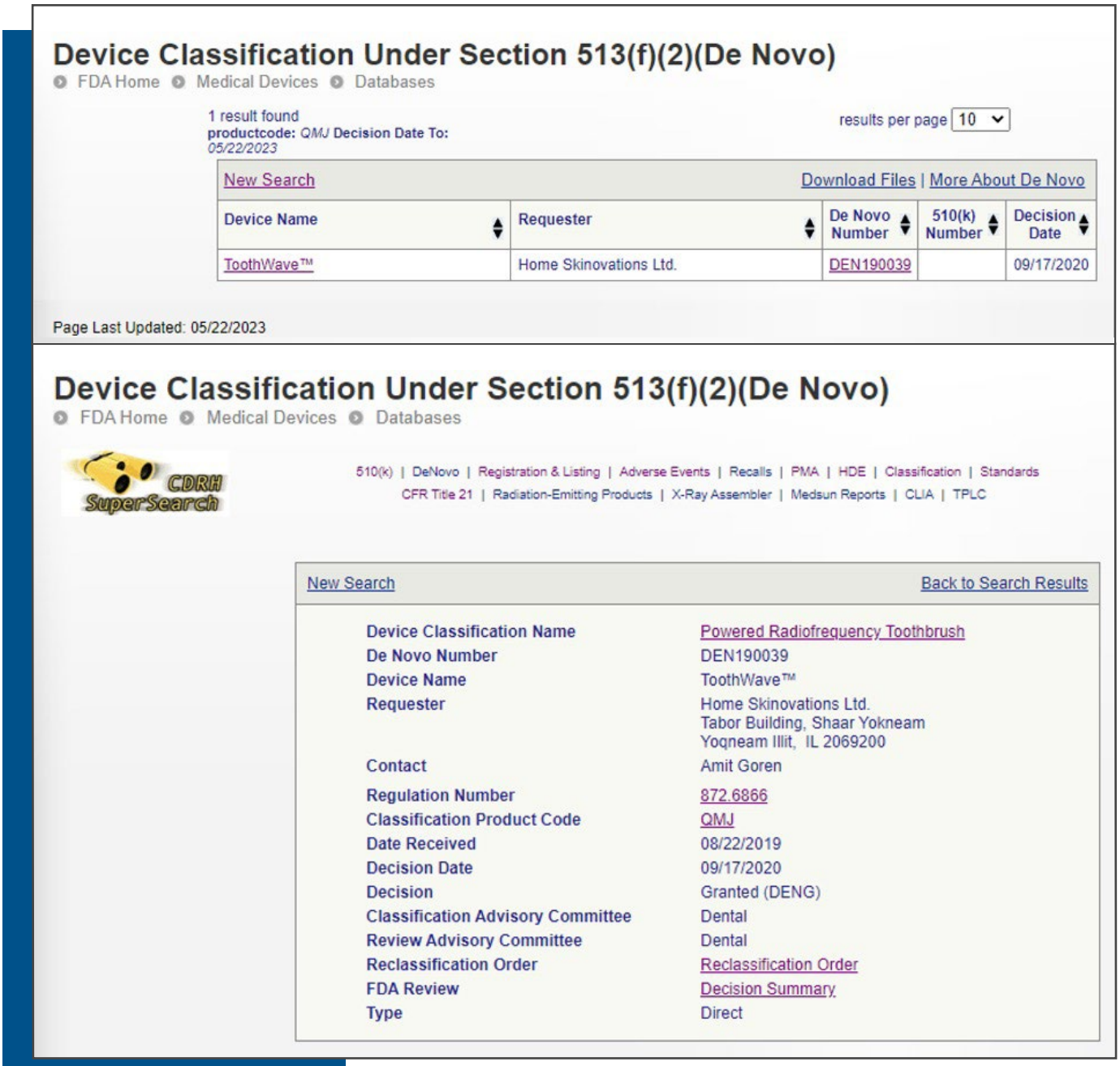
In this example, unless a manufacturer is making the most common type of bedside infusion pump — typically found in a hospital or similar healthcare facility — that is classified under product code FRN (pump, infusion), the manufacturer will need to look more closely at the other, more specialized types of infusion pumps that fall under product codes LZG, LZH, MEA, MEB, OPP, PKP, QJY and MRH to determine whether their device is more accurately described under one of these other product codes. In this case, which will likely require looking at 510(k) summary documents to read the description of those devices that are classified under product codes LZG, LZH, MEA, MEB and MRH, as there is no additional information in the form of definition, physical state, technical method and target area for these devices on their respective product classification pages like there is for product codes OPP, PKP and QJY. Part (a) of 880.5725 describes the most common type of infusion pump, product code FRN, while product codes LZF, LDR, LGZ, LHF, MHD, MRZ, PHC and PMS are other types of devices or accessories that are used with infusion pumps as identified by their product code names, seen in the table in **Figure 20**.

Additional information on the product classification page

As previously discussed in this white paper, when a product classification page has additional information for definition, physical state, technical method and target area for a particular product code, it likely means one of the following:

- The product code and regulation number were established under a De Novo pathway. This can easily be confirmed by placing the product code for the device in the product code field in the De Novo database and running a search to see if a DEN number is found, as seen in Figure 21 for product code QMJ (powered radiofrequency toothbrush) and CFR 872.6866.
- The FDA added the product code to an existing regulation number that has more than one product code in that regulation.
- The FDA has not written a regulation for the product code that applies to:
  - Unclassified (pre-amendment) devices
  - Not-classified devices
  - HDE devices
  - Certain Class III devices

Figure 21 – De Novo Database Results Using Product Code QMJ



Device Classification Under Section 513(f)(2)(De Novo)

FDA Home › Medical Devices › Databases

1 result found
productcode: *QMJ* **Decision Date To:** *05/22/2023*

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Device Name	Requester	De Novo Number	510(k) Number	Decision Date
ToothWave™	Home Skinovations Ltd.	DEN190039		09/17/2020

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Device Classification Under Section 513(f)(2)(De Novo)

FDA Home › Medical Devices › Databases

CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

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Device Classification Name	Powered Radiofrequency Toothbrush
De Novo Number	DEN190039
Device Name	ToothWave™
Requester	Home Skinovations Ltd. Tabor Building, Shaar Yokneam Yoqneam Illit, IL 2069200
Contact	Amit Goren
Regulation Number	872.6866
Classification Product Code	QMJ
Date Received	08/22/2019
Decision Date	09/17/2020
Decision	Granted (DENG)
Classification Advisory Committee	Dental
Review Advisory Committee	Dental
Reclassification Order	Reclassification Order
FDA Review	Decision Summary
Type	Direct

Introducing new technology to an existing class of device

When innovative technology is introduced to an existing class of device that is low-to moderate-risk, there is the potential for a De Novo pathway to be required by the FDA to commercialize that device in the U.S. Product code QMJ (powered radiofrequency toothbrush) and CFR 872.6866 as discussed above and seen in **Figure 21** is a good example of this.

In the above example for the powered radiofrequency toothbrush, the device manufacturer added radiofrequency technology to a powered toothbrush. A powered toothbrush is a Class I 510(k)-exempt device under product code JEQ (toothbrush, powered) and regulation number 872.6865, but subject to the 510(k) limitations in CFR 872.9 for dental devices. The intended use of a toothbrush (manual, powered or powered with radiofrequency technology) is to remove adherent plaque and food debris from the teeth to reduce tooth decay. While it's possible the FDA could have requested that the manufacturer of the powered radiofrequency toothbrush submit a 510(k) for their device under product code JEQ because its technology operates using a different fundamental scientific technology than a legally marketed powered toothbrush, it appears that the radiofrequency technology used in this device was different enough to require a De Novo be submitted to the FDA, thus creating the new Class II device under product code QMJ and CFR 872.6866.

Summary and conclusion

The FDA's medical device classification system is one of the most complicated when compared to other countries, with 16 review panels, more than 6,500 product codes, more than 1,700 regulation numbers, and devices identified as unclassified, Class I, Class II, Class III, not classified and HDE, with eight routes to commercialization in the U.S. – 510(k)-exempt, 510(k), De Novo, PMA, HDE, EUA, enforcement discretion and contact ODE. Understanding how your device is classified is the first step toward ensuring that you have identified the correct route for commercializing it in the U.S. and have developed a successful regulatory strategy.

While many devices are easy to classify in the FDA's device classification system, many are not. All device classifications need to be carefully evaluated before proceeding with a regulatory submission to the FDA. Emergo by UL can assist you in classifying your medical device or contacting the FDA for assistance under their **513(g) Request for Information**[10] (classification) process.

End Notes

1. At the time this White Paper was published by Emergo by UL (May 2023).
2. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=884.5305
3. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=884.5305
4. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN170073
5. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=892.2055
6. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN180001
7. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN200055
8. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN160056
9. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=888.3695
10. https://www.fda.gov/media/78456/download

About the author

Stuart R. Goldman has over thirty years of combined RA/QA experience in medical devices, including fifteen years in industry working on high-risk Class III/II implantable devices. At Emergo by UL, Stuart focuses on the United States market and has extensive expertise in device classification and testing requirements; regulatory pathway strategies; Q-Submissions and clearance of over forty 510(k)s and submission of over twenty 513(g)s.

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