US

Medical Device Testing Requirements for 510(k) Submissions

Identifying the Correct FDA Guidance Documents and Standards



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How Do I Know What to Test?

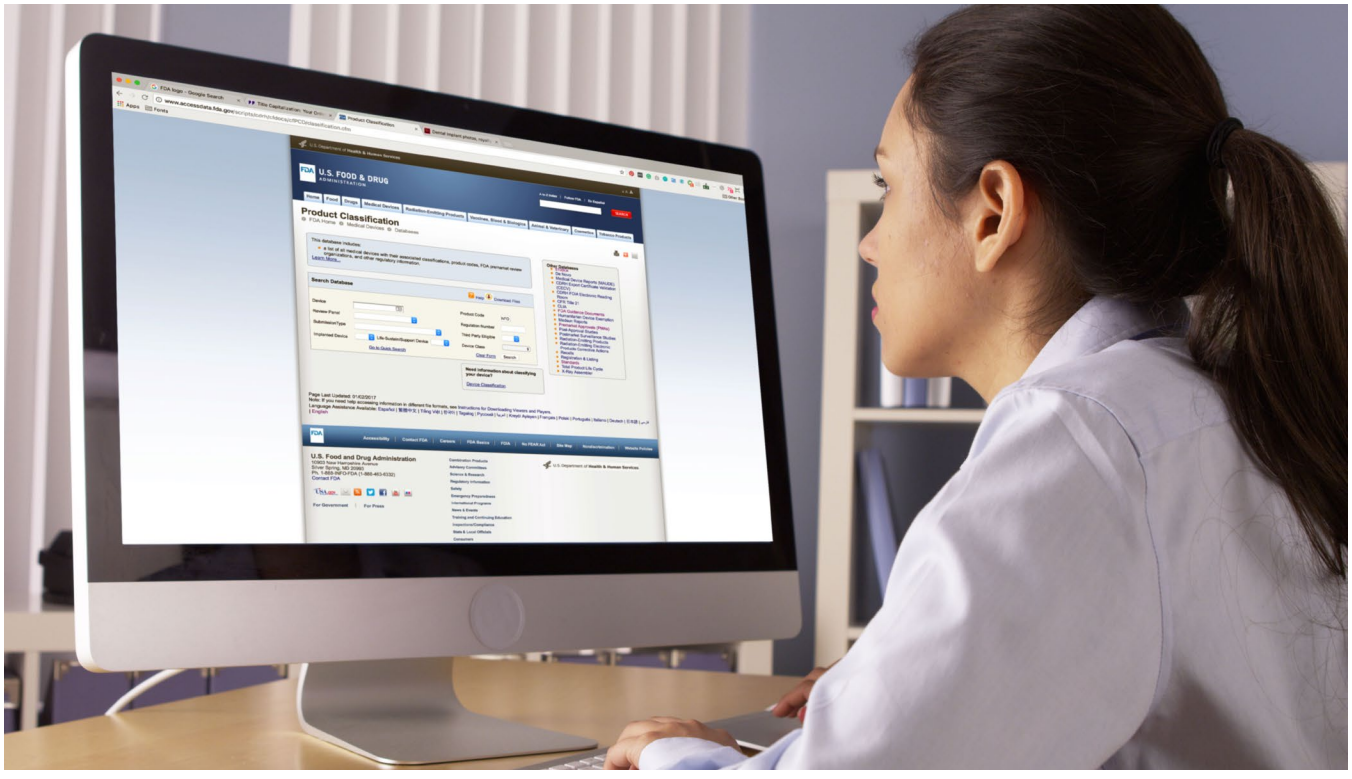
Clients who engage Emergo for FDA 510(k) submission consulting often ask what testing is required by the FDA to clear their device. While testing requirements are easy to determine for some devices, other devices require intensive research.

It is very important to identify the correct testing requirements. Failure to do so could result in a longer 510(k) review time if the FDA sends an Additional Information (AI) Request asking for test data that was not anticipated or budgeted. If you cannot provide the requested test data in a timely manner, you might even have to withdraw your 510(k) submission.

This article does not discusses how the FDA uses recognized consensus standards to make substantial equivalence determinations in 510(k) submissions. To better understand this process and other matters related to the use of standards, consult the following FDA guidance documents:

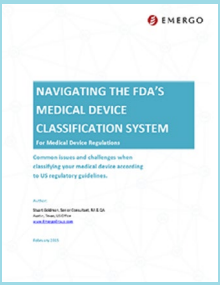
- CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition
- Guidance for Industry and for FDA Staff: Use of Standards in Substantial Equivalence Determinations
- Frequently Asked Questions on Recognition of Consensus Standards

We will discuss how to identify the correct testing requirements and performance standards for your device using FDA databases. Determine the correct standards and guidances for your device before starting testing activities, which should be done long before submitting a 510(k). We will also look at other methods used to determine relevant testing information for predicate devices outside normal FDA databases.



Classifying Your Medical Device Under the US FDA

Before a device sponsor can determine the testing requirements for their device, they must correctly classify their device according to the FDA's Product Classification database. They must also complete all design and development activities as defined in 21CFR Part 820.30, Design Controls, as any test data submitted in a 510(k) should be conducted on a finished device, or a device that fully represents the final design.



For those not familiar with how to classify a medical device, my previous article titled Navigating the FDA's Medical Device Classification System explains how to classify a medical device under the FDA's product classification system.

The FDA has three classes for medical devices (Class I, Class II, and Class III) based on the level of risk the device poses to the user. Class I devices pose the least risk to the user, while Class III devices pose the highest risk. All medical devices have a certain degree of risk associated with their use, as no device is considered perfectly safe. The entity named on the device's label is responsible for managing those risks, and demonstrating that their device is both safe and effective for its intended use. One way to accomplish this for moderate to high-risk devices is to test the device against a known standard(s) that subjects it to simulated use conditions. Many devices are actually tested to worst case conditions to assess the risk of extreme use situations.

Most Class I devices are exempt from the 510(k) process, while most Class III devices require Premarket Approval (PMA), which is a more rigorous regulatory pathway than a 510(k). A PMA requires clinical data, as well as performance data, to prove safety and effectiveness. To help manage the risk a device poses to a patient or user, the FDA imposes their Regulatory Controls on the manufacturer of the device, which vary by classification.

Home-use devices

Home-use devices often present hazardous situations for the layperson. Devices sold Over-the-Counter (OTC) or by prescription are usually self-administered by a layperson in a home setting. A popular example of such a product is a hand-held, light-based laser device to treat full-face wrinkles.

The FDA requires extensive testing for electrical safety, electromagnetic compatibility, and biocompatibility, as well as other specialized tests that may be applicable, for home-use devices. The test data obtained from these different tests is included in the 510(k) submission. The FDA critically assesses the test data during their review to determine if the subject device is substantially equivalent to the predicate device.

With the product classification out of the way and assumed correct, I will demonstrate methods for finding the applicable testing requirements (and standards). These examples highlight some of the techniques and pitfalls you might encounter when using the various FDA databases. Always be mindful of the FDA's Special Controls when dealing with testing requirements. Two of the most important special controls are the FDA's Guidance Documents (aka guidelines) and Recognized Consensus Standards (aka performance standards).

Vertical vs. horizontal standards

Many FDA guidance documents and performance standards are product code specific ("vertical") because they apply to a specific type of device (e.g., dental implant; product code DZE). However, other guidance documents and performance standards are not product code specific ("horizontal") and cover several different types of devices across various Device Classification Panels.

Vertical guidance documents are particularly important when making a 510(k) submission. In addition to the testing requirements for that specific device, vertical guidance documents contain other valuable information required to clear the device, such as special product labeling requirements, identified risks and hazards that need to be considered, if clinical data will be required in the submission, etc.

Each device sponsor should approach their testing strategy with a master test plan, so that all known tests can be identified and budgeted. Manufacturers are encouraged to discuss their test strategy with the FDA prior to starting any testing, via a Pre-Submission meeting. This is especially important if any testing is unique to your device and not covered under any known performance standard, whether it's an FDA recognized consensus standard or not.

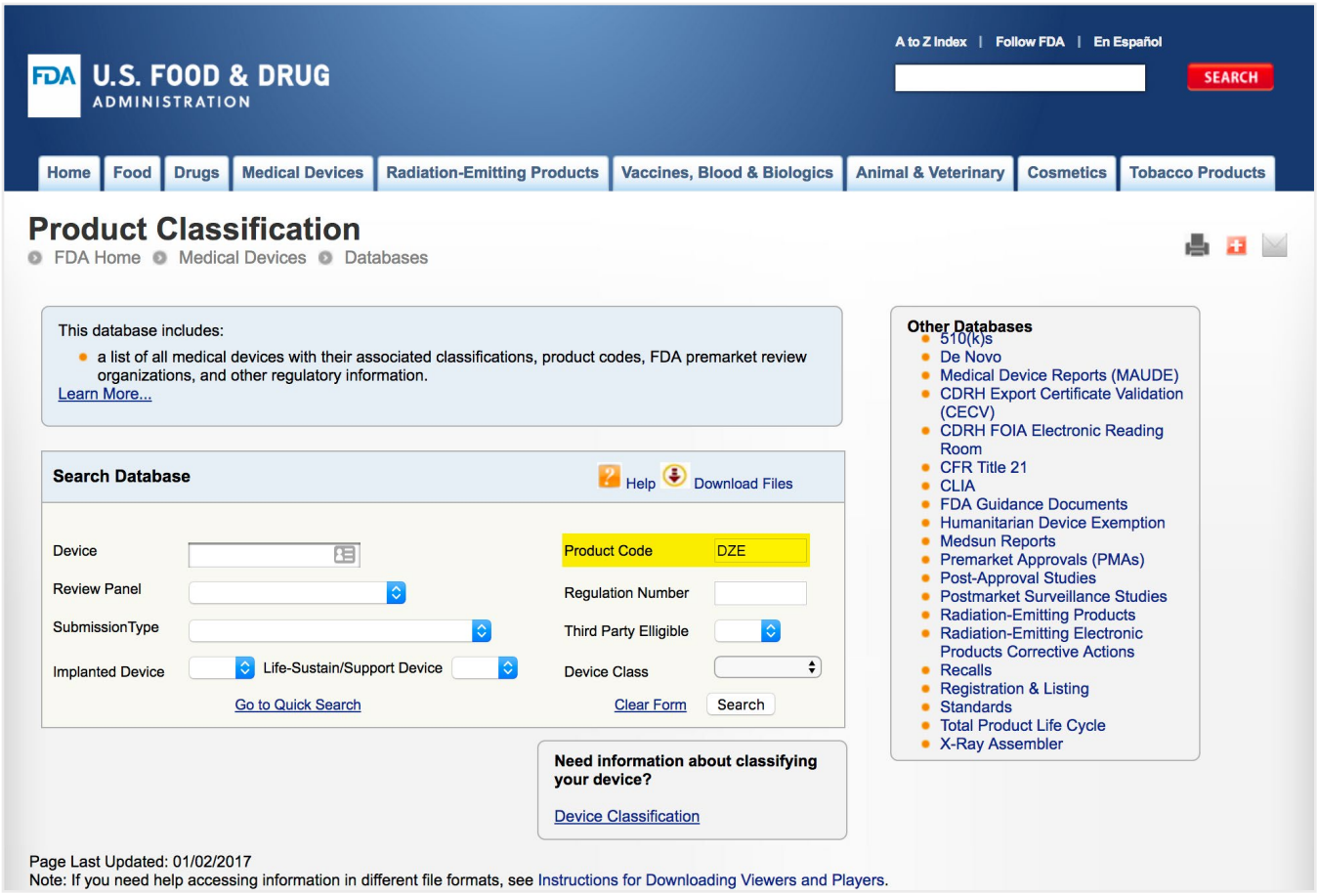
How to Use and Understand FDA Databases - Example 1

Let's look at some specific examples of how to identify the testing requirements for different devices.

Example 1 – Product code DZE (Implant, Endosseous, Root-Form)

Using the FDA's product classification database, insert "DZE" into the "Product Code" field and click on the "Search" button in the lower right of the screen, as shown in Figure 1. All of the relevant FDA regulatory information for this device is shown in Figure 2. We suggest using the product classification database as the starting point when searching for product code specific guidance documents and performance standards, as these should come up in the search if they exist.

Figure 1 – Product Classification Database Search for an Endosseous Dental Implant (DZE)



Source: http://www.accessdata.fda.gov/

Figure 2 – FDA Regulatory Information for Product Code DZE (Including Guidance and Standards)

Product Classification

FDA Home › Medical Devices › Databases

New Search | Back To Search Results

Device	Implant, Endosseous, Root-Form
Regulation Description	Endosseous dental implant.
Regulation Medical Specialty	Dental
Review Panel	Dental
Product Code	DZE
Premarket Review	Office of Device Evaluation (ODE) Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) Dental Devices Branch (DEDB)
Submission Type	510(k)
Regulation Number	872.3640
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Recognized Consensus Standards

- 2-165 AAMI ANSI ISO 10993-14:2001/(R) 2011
  Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products form ceramics
- 2-170 ISO 10993-14 First edition 2001-11-15
  Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics
- 4-86 ADA ANSI Specification No.38 2000 (R2015)
  Metal-Ceramic Dental Restorative Systems
- 4-195 ISO 14801 Second edition 2007-11-15
  Dentistry-Implants-Dynamic fatigue test for endosseous dental implants
- 4-212 ISO 7405 Second edition 2008-12-15
  Dentistry - Evaluation of biocompatibility of medical devices used in dentistry [Including: Amendment 1 (2013)]
- 8-57 ISO 5832-2:1999
  Implants for surgery -- Metallic materials - Part 2: Unalloyed titanium
- 8-58 ISO 5832-3:1996
  Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
- 8-195 ASTM F2024-10
  Standard Practice for X-Ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxyapatite Coatings
- 8-354 ASTM F1377-13
  Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)
- 8-406 ISO 5832-11 Second edition 2014-09-15
  Implants for surgery -- Metallic materials -- Part 11: Wrought titanium 6-aluminium 7-niobium alloy

Guidance Document

- Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff

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

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Source: http://www.accessdata.fda.gov/

This is a good example of when the FDA's product classification database yields a lot of valuable information on a device: ten standards and one guidance document are listed. Two of those standards (ADA/ANSI Specification No.38, and ISO 14801) are vertical and unique to dental implants, dental abutments, and a few other dental devices. The other eight standards are horizontal, and may or may not be applicable to a particular dental implant depending on the specific characteristics of the device (e.g., the material, surface finish, etc.).

However, this list does not include horizontal standards that could also apply to dental implants, such as sterilization and packaging. Finding those horizontal standards requires a separate search.

Using guidance documents to your advantage

Also shown in **Figure 2** is the FDA's guidance document specific to endosseous dental implants: Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments. This guidance document also covers dental abutments (product code NHA; regulated within 872.3630 as a Class II device) as shown in **Figure 3**. Dental abutments are often sold with dental implants as a system, and cleared under the same 510(k). Or, they can be cleared and sold separately.

A product code specific guidance document is a big advantage when making a 510(k) submission. The FDA is essentially telling the device sponsor what they expect to see in their 510(k). Assuming the device sponsor has read the guidance document, understands what is being requested, and presents that information (and test data) in their submission, there should (theoretically) be no unexpected questions from the FDA.

The guidance document for dental implants (and abutments) listed above is a good example of the level of detailed information, including specific test data, the FDA expects to see in a 510(k) submission. If the device sponsor fails to address these key areas, it could significantly increase the 510(k) review time or force the device sponsor to withdraw their submission if they cannot supply the requested additional information in a timely manner. This FDA guidance document references the potential need to submit clinical data (see Section 12, Clinical Studies) if the implants are within a certain size range, are made from novel materials or manufacturing methods, among other things.

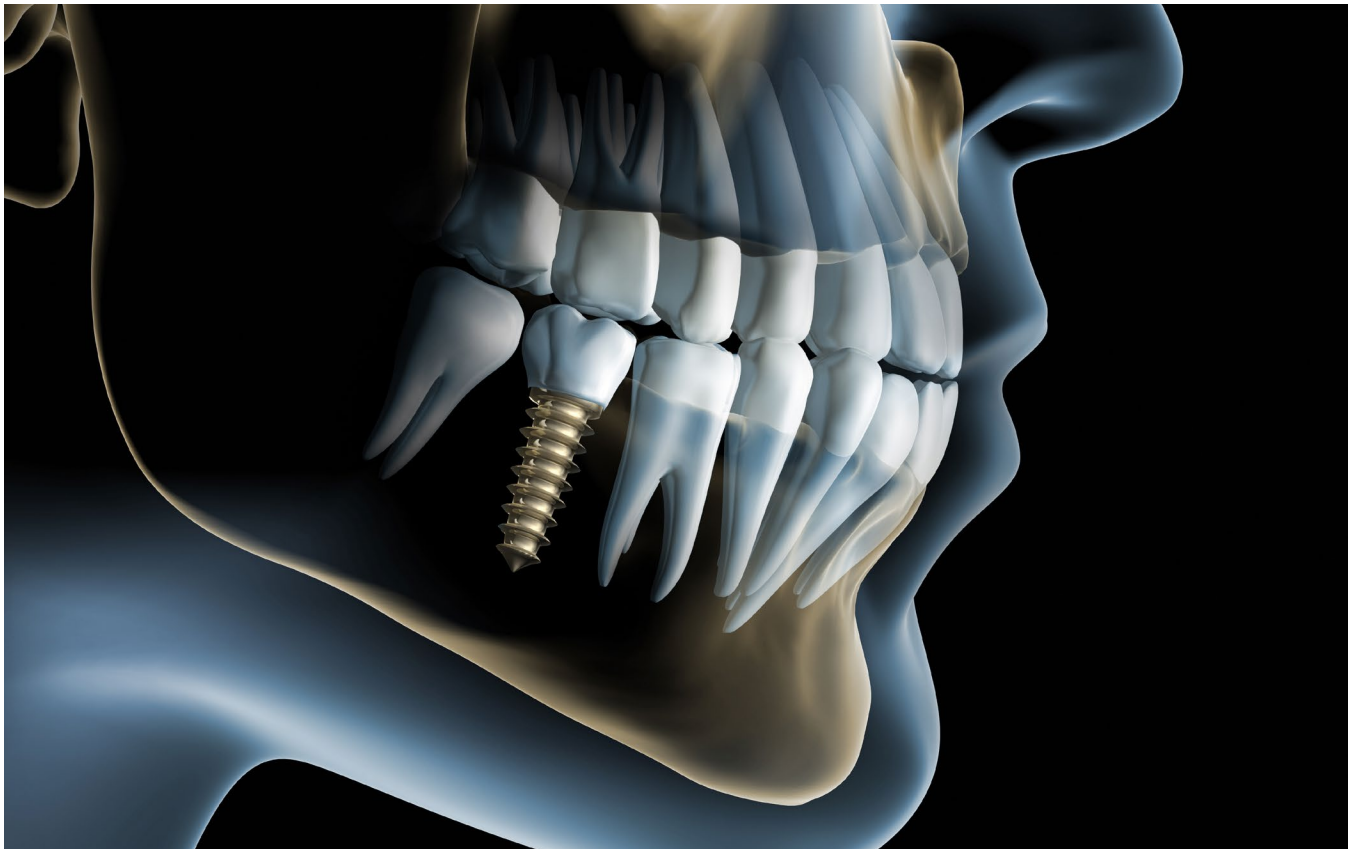
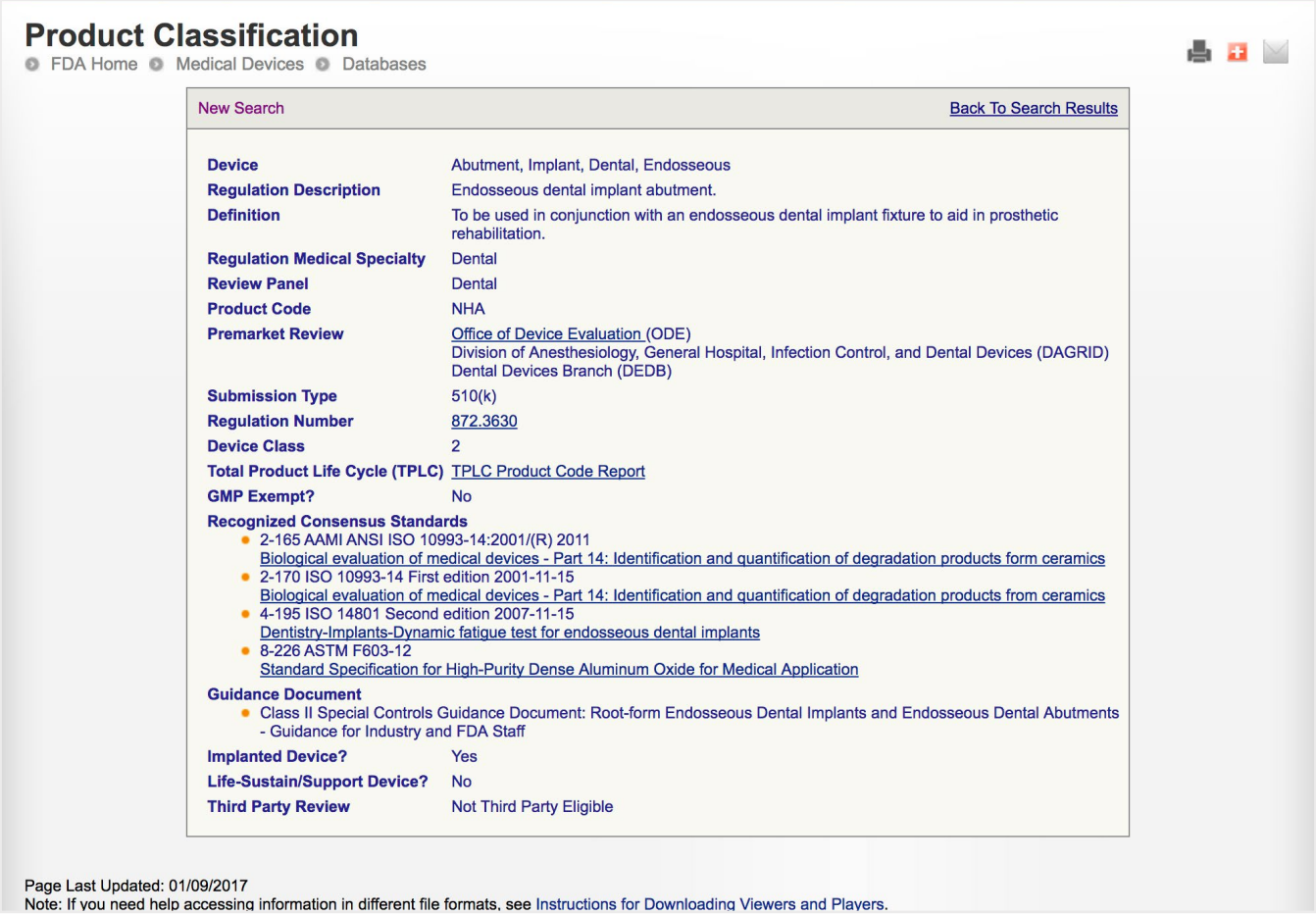


Figure 3 – Product Classification Database Search for a Dental Abutment (NHA)



Product Classification

FDA Home › Medical Devices › Databases

New Search | Back To Search Results

Device	Abutment, Implant, Dental, Endosseous
Regulation Description	Endosseous dental implant abutment.
Definition	To be used in conjunction with an endosseous dental implant fixture to aid in prosthetic rehabilitation.
Regulation Medical Specialty	Dental
Review Panel	Dental
Product Code	NHA
Premarket Review	Office of Device Evaluation (ODE) Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) Dental Devices Branch (DEDB)
Submission Type	510(k)
Regulation Number	872.3630
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Recognized Consensus Standards

- 2-165 AAMI ANSI ISO 10993-14:2001/(R) 2011
  Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products form ceramics
- 2-170 ISO 10993-14 First edition 2001-11-15
  Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics
- 4-195 ISO 14801 Second edition 2007-11-15
  Dentistry-Implants-Dynamic fatigue test for endosseous dental implants
- 8-226 ASTM F603-12
  Standard Specification for High-Purity Dense Aluminum Oxide for Medical Application

Guidance Document

- Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff

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

Page Last Updated: 01/09/2017
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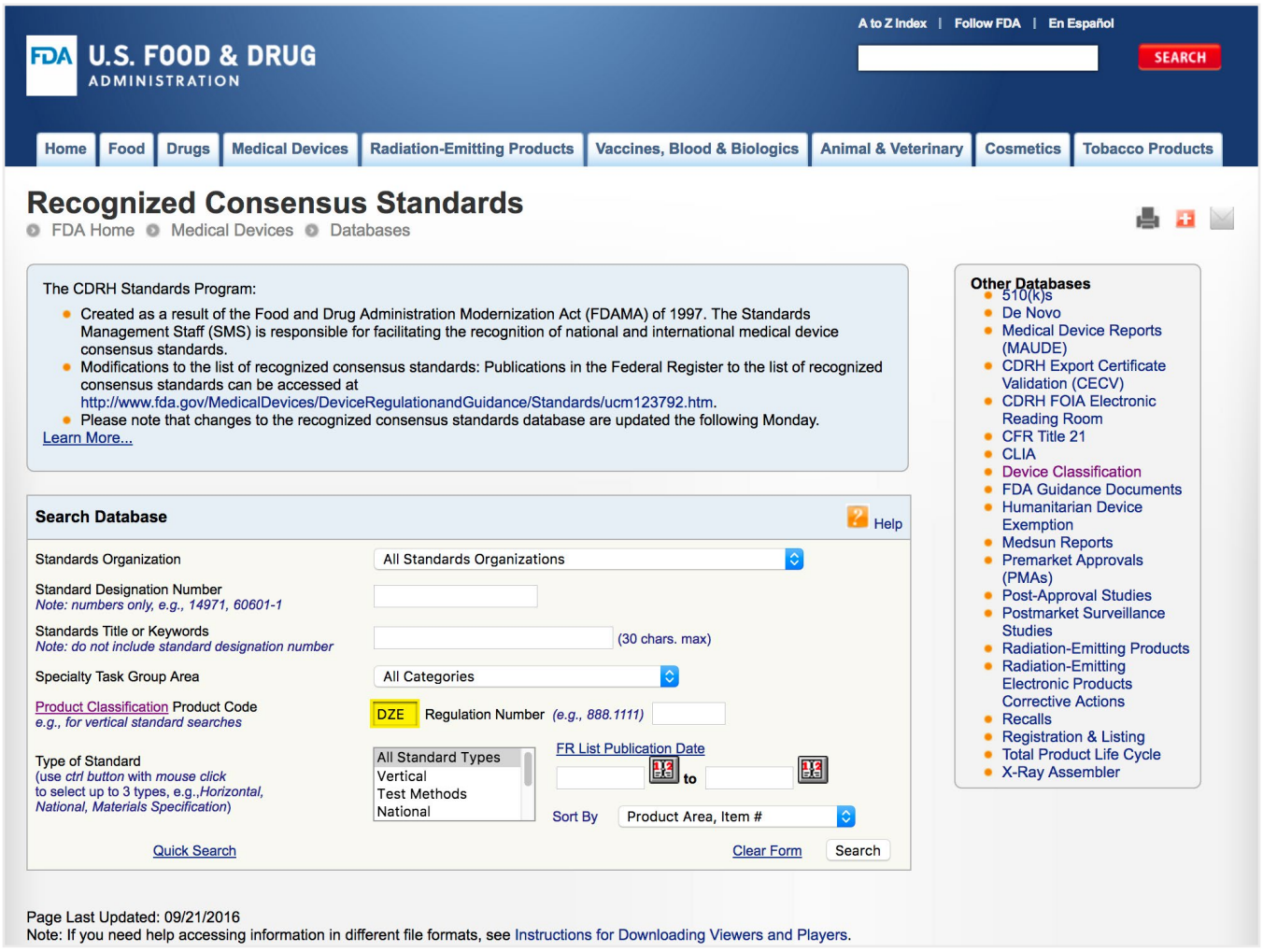
Source: http://www.accessdata.fda.gov/

All the standards for dental implants obtained from the product classification database search shown in **Figure 2** can also be found by searching in the FDA's recognized consensus standards database. Again, inserting "DZE" into the "Product Code" field and clicking on the "Search" button, as seen in **Figures 4-5** below, extracts the same results shown in **Figure 2** above. However, this method alone will not find the FDA's guidance document for dental implants, which requires a separate search using the FDA's guidance document database, shown in **Figure 6**.

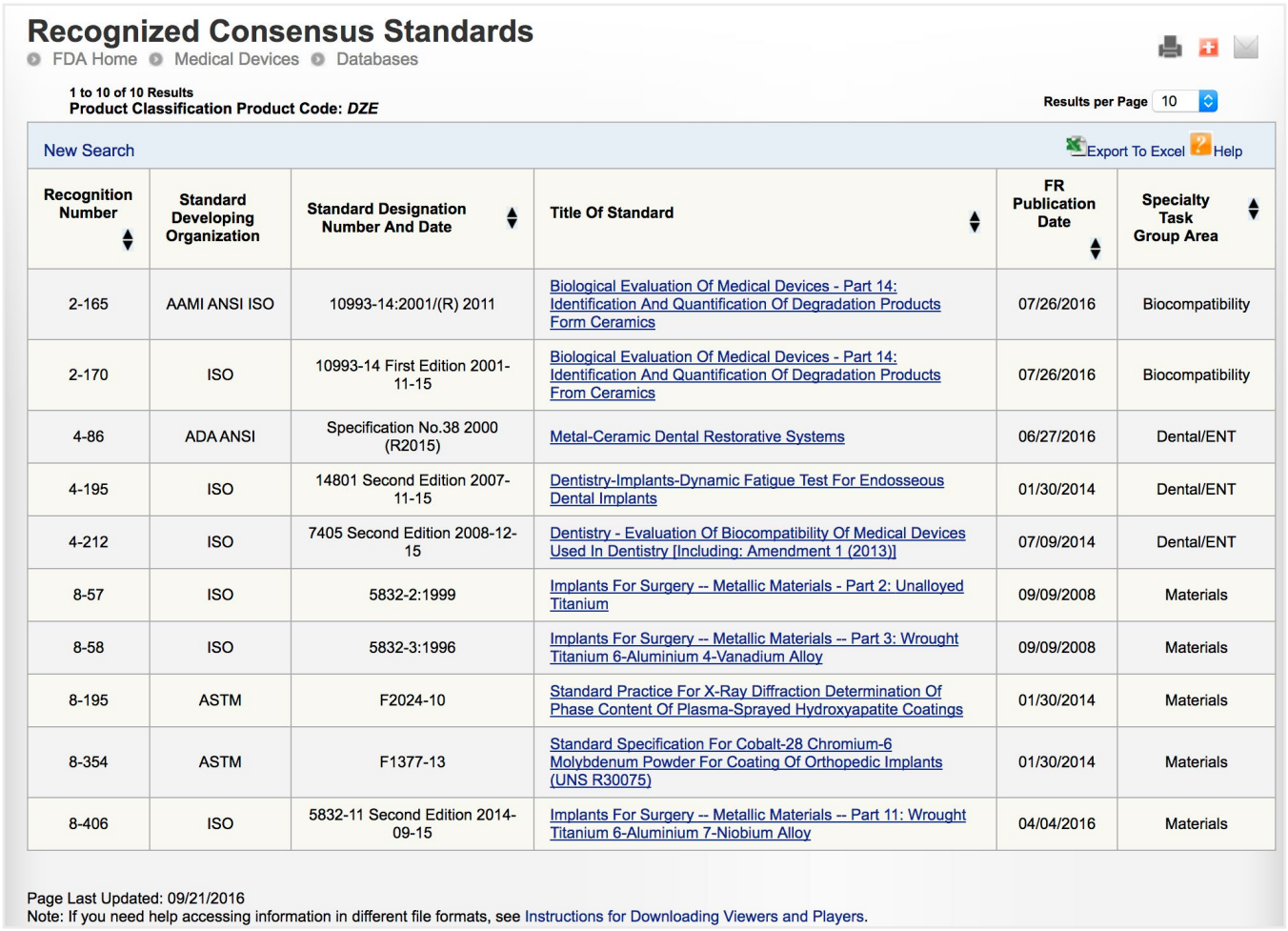
How to Use and Understand FDA Databases - Example 1

Figure 4 – Recognized Consensus Standards Database Search for an Endosseous Dental Implant (DZE)



Source: http://www.accessdata.fda.gov/

Figure 5 – Extracted Performance Standards for Product Code DZE



Recognized Consensus Standards

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1 to 10 of 10 Results
Product Classification Product Code: *DZE*

Results per Page 10

New Search | Export To Excel | Help

Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard	FR Publication Date	Specialty Task Group Area
2-165	AAMI ANSI ISO	10993-14:2001/(R) 2011	Biological Evaluation Of Medical Devices - Part 14: Identification And Quantification Of Degradation Products Form Ceramics	07/26/2016	Biocompatibility
2-170	ISO	10993-14 First Edition 2001-11-15	Biological Evaluation Of Medical Devices - Part 14: Identification And Quantification Of Degradation Products From Ceramics	07/26/2016	Biocompatibility
4-86	ADA ANSI	Specification No.38 2000 (R2015)	Metal-Ceramic Dental Restorative Systems	06/27/2016	Dental/ENT
4-195	ISO	14801 Second Edition 2007-11-15	Dentistry-Implants-Dynamic Fatigue Test For Endosseous Dental Implants	01/30/2014	Dental/ENT
4-212	ISO	7405 Second Edition 2008-12-15	Dentistry - Evaluation Of Biocompatibility Of Medical Devices Used In Dentistry [Including: Amendment 1 (2013)]	07/09/2014	Dental/ENT
8-57	ISO	5832-2:1999	Implants For Surgery -- Metallic Materials - Part 2: Unalloyed Titanium	09/09/2008	Materials
8-58	ISO	5832-3:1996	Implants For Surgery -- Metallic Materials -- Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy	09/09/2008	Materials
8-195	ASTM	F2024-10	Standard Practice For X-Ray Diffraction Determination Of Phase Content Of Plasma-Sprayed Hydroxyapatite Coatings	01/30/2014	Materials
8-354	ASTM	F1377-13	Standard Specification For Cobalt-28 Chromium-6 Molybdenum Powder For Coating Of Orthopedic Implants (UNS R30075)	01/30/2014	Materials
8-406	ISO	5832-11 Second Edition 2014-09-15	Implants For Surgery -- Metallic Materials -- Part 11: Wrought Titanium 6-Aluminium 7-Niobium Alloy	04/04/2016	Materials

Page Last Updated: 09/21/2016
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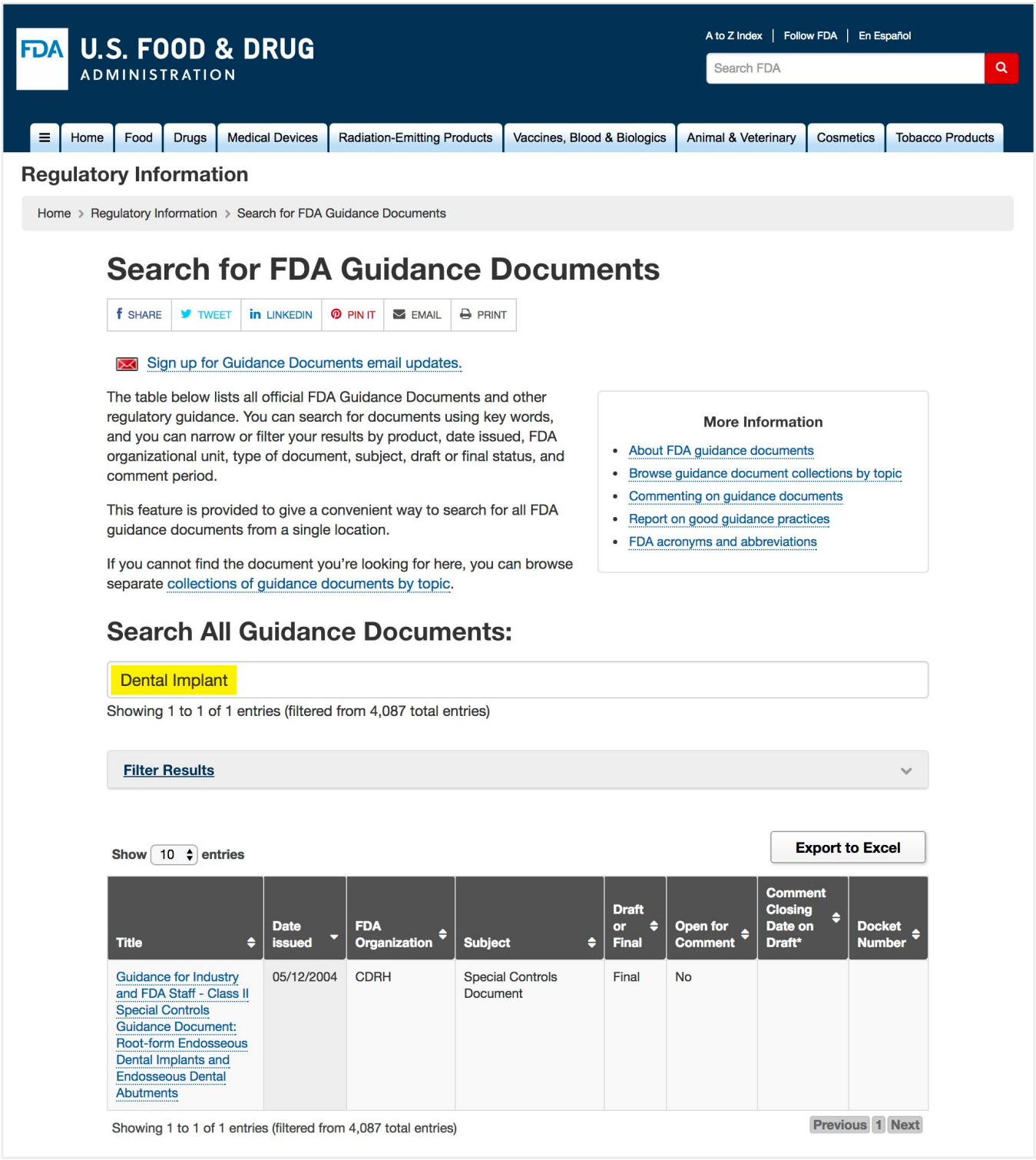
Source: http://www.accessdata.fda.gov/

Figure 6 – Guidance Document Database Search for "Dental Implant"



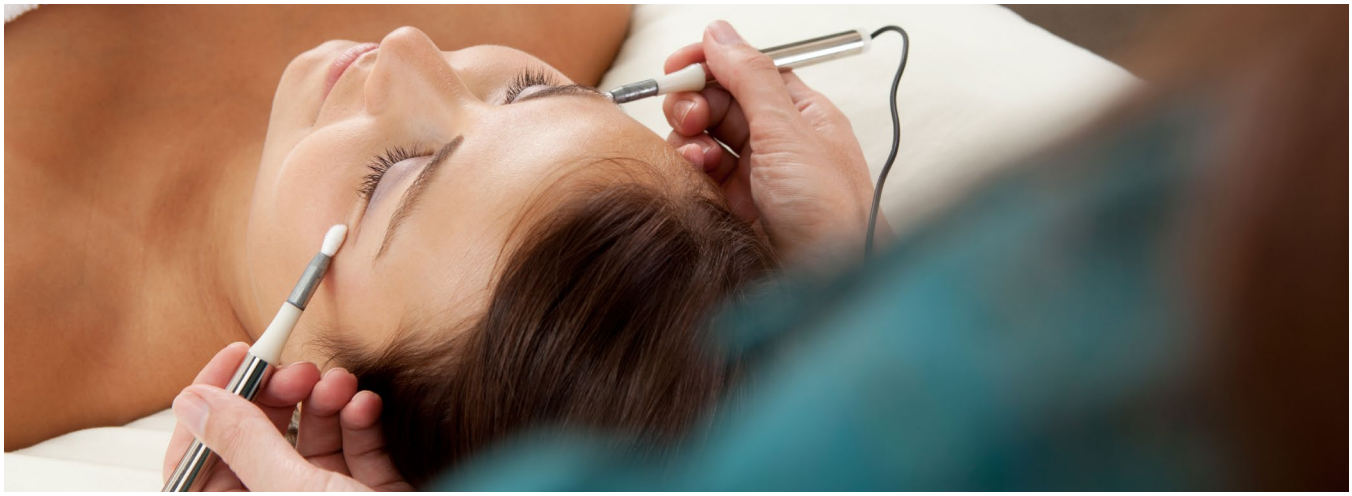
Source: http://www.fda.gov/

How to Use and Understand FDA Databases - Example 2

Example 2 – Product Code NFO (Transcutaneous Electrical Stimulator for Aesthetic Purposes)

Figure 7 shows the relevant regulatory information for a *transcutaneous electrical stimulator for aesthetic purposes* extracted from the FDA's product classification database (product code NFO; regulated within 882.5890 as a Class II device). These are typically hand-held OTC devices used by laypersons in a home setting, and cleared for "facial stimulation and cosmetic use."

In **Figure 7**, no FDA guidance documents or performance standards are referenced, as in Example 1 for dental implants. Additionally, no relevant performance standards were extracted when searching in the FDA's standards database under product code "NFO." Searching the FDA's guidance document database using key search terms (i.e., "aesthetic," "transcutaneous," "electrical," and "stimulator") does not return a relevant guidance document for this type of device (these terms located guidance documents for several unrelated devices). However, an unsuccessful search does not indicate that extensive device testing is not required to clear a *transcutaneous electrical stimulator for aesthetic purposes*.



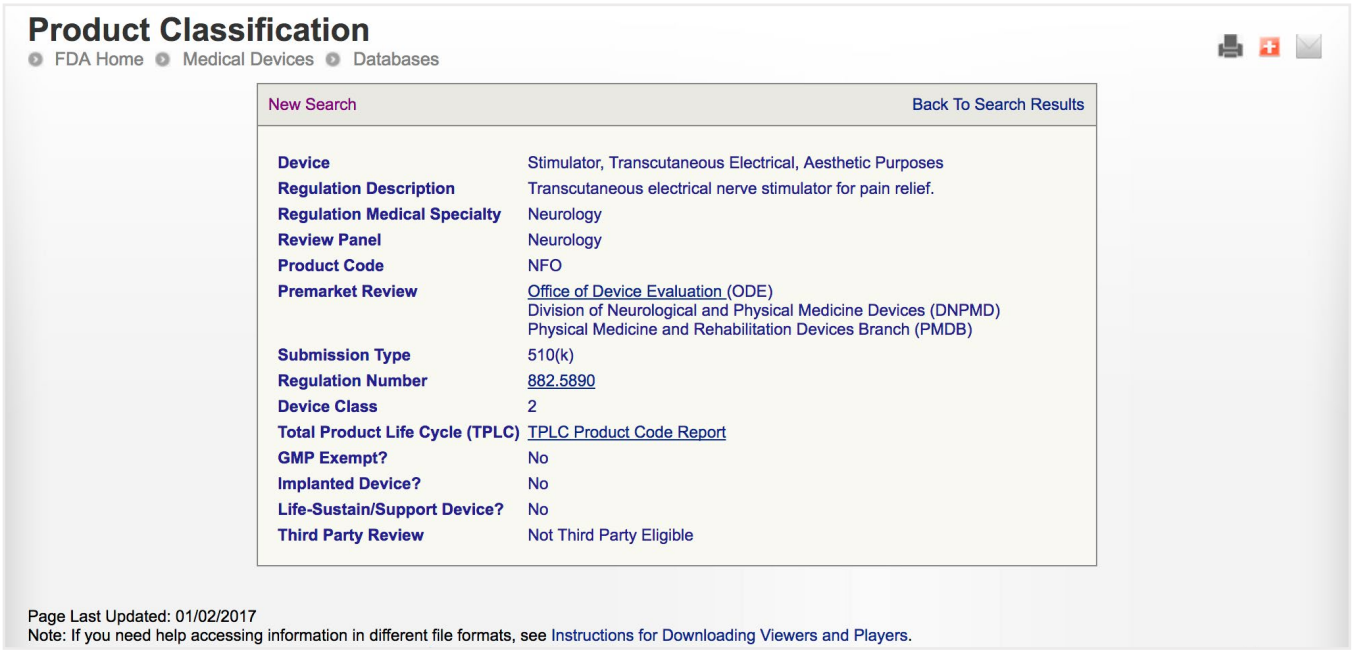
Product codes with no linked guidances or standards

Many product codes have no vertical guidance documents or performance standards linked to them. Unless you know how to look further in other FDA databases (or elsewhere), or have experience clearing similar devices, you may not find them and assume testing is not required. However, it's important to remember that the FDA has not issued guidance documents for many product codes.

In situations where the FDA's product classification, guidance document, and recognized consensus standards databases do not reveal the testing requirements for a particular device, use the FDA's 510(k) Premarket Notification database. This database contains information about testing completed for previously cleared devices under the same product code. The FDA will likely require similar testing for the subject device. If the device sponsor has already selected a predicate device for their 510(k) submission, reviewing the 510(k) summary in the FDA database is a good place to start the search.

Using product code NFO and performing this type of search shows twenty devices cleared from 2001-2016, as seen in **Figures 8-9**.

Figure 7 – FDA Regulatory Information for Product Code NFO



Product Classification
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New Search | Back To Search Results

Device	Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Regulation Description	Transcutaneous electrical nerve stimulator for pain relief.
Regulation Medical Specialty	Neurology
Review Panel	Neurology
Product Code	NFO
Premarket Review	Office of Device Evaluation (ODE) Division of Neurological and Physical Medicine Devices (DNPMD) Physical Medicine and Rehabilitation Devices Branch (PMDB)
Submission Type	510(k)
Regulation Number	882.5890
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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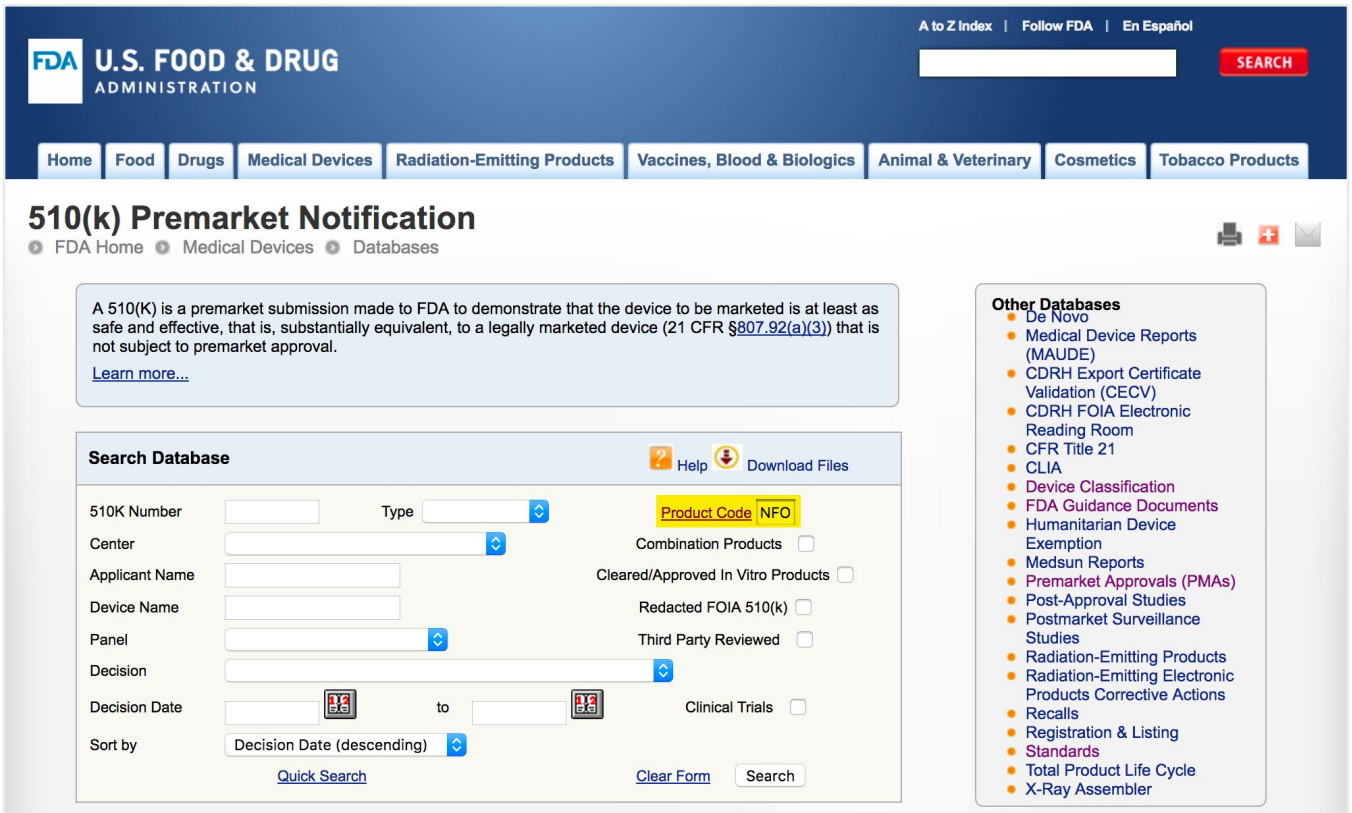
Source: http://www.accessdata.fda.gov/

Figure 8 – Predicate Device 510(k) Database Search for Product Code NFO



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510(k) Premarket Notification
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A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR §807.92(a)(3)) that is not subject to premarket approval.
Learn more...

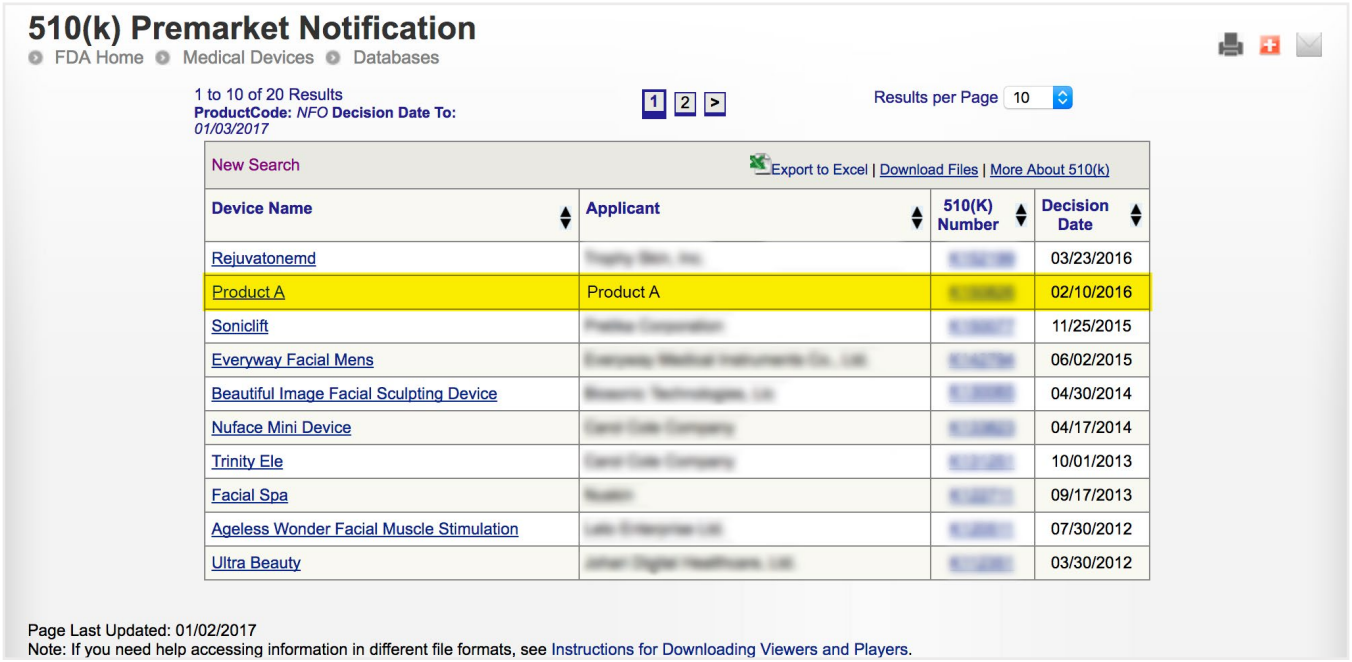
Search Database — Help | Download Files

510K Number | Type | Product Code NFO
Center | Combination Products
Applicant Name | Cleared/Approved In Vitro Products
Device Name | Redacted FOIA 510(k)
Panel | Third Party Reviewed
Decision
Decision Date | to | Clinical Trials
Sort by: Decision Date (descending)
Quick Search | Clear Form | Search

Other Databases
- De Novo
- Medical Device Reports (MAUDE)
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- FDA Guidance Documents
- Humanitarian Device Exemption
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Registration & Listing
- Standards
- Total Product Life Cycle
- X-Ray Assembler

Source: http://www.accessdata.fda.gov/

Figure 9 – Extracted 510(k) Summaries for Product Code NFO



510(k) Premarket Notification

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1 to 10 of 20 Results
ProductCode: *NFO* **Decision Date To:** *01/03/2017*

1 2 >

Results per Page 10

New Search | Export to Excel | Download Files | More About 510(k)

Device Name	Applicant	510(K) Number	Decision Date
Rejuvatonemd	[redacted]	[redacted]	03/23/2016
Product A	Product A	[redacted]	02/10/2016
Soniclift	[redacted]	[redacted]	11/25/2015
Everyway Facial Mens	[redacted]	[redacted]	06/02/2015
Beautiful Image Facial Sculpting Device	[redacted]	[redacted]	04/30/2014
Nuface Mini Device	[redacted]	[redacted]	04/17/2014
Trinity Ele	[redacted]	[redacted]	10/01/2013
Facial Spa	[redacted]	[redacted]	09/17/2013
Ageless Wonder Facial Muscle Stimulation	[redacted]	[redacted]	07/30/2012
Ultra Beauty	[redacted]	[redacted]	03/30/2012

Page Last Updated: 01/02/2017
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Source: http://www.accessdata.fda.gov/

Read the 510(k) Summary for a few devices for any relevant information about the testing performed on them. We recommend looking at 510(k) Summaries for the most recently cleared devices for relevant technical information, as opposed to devices cleared longer than five years ago.

The substantial equivalence table in the 510(k) Summary for Product A, which was cleared in 2016, references a number of tests (highlighted in yellow) performed to clear this device.

Figure 10 – Partial Image of Substantial Equivalence Table Extracted from Product A 510(k) Summary

Elements of Comparison	Product A	Predicate Device
510(k) Number	Product A: 510(k) Number	Product B: 510(k) Number
Regulation Number	21 C.F.R 882.5890	21 C.F.R 882.5890
Regulation Name	Transcutaneous Electrical Nerve Stimulator	Transcutaneous Electrical Nerve Stimulator
Regulatory Class	Class II	Class II
Product Code	NFO	NFO
Intended use	Stimulate the face; skin toning	Stimulate the face; skin toning
Indications for Use	Intended for facial stimulation and is indicated for-over-the counter cosmetic use.	Intended for facial stimulation and is indicated for-over-the counter cosmetic use.
Technological Characteristics	Product A is a hand-held device intended to apply low level electrical impulses to strategic locations on the face. Product A probes are designed for optimal contact with the face.	Product B is a Facial Toning Device intended for facial stimulation. The device measures 7" L x 2.5" W x1" D. Its outer case is injection molded of thermoplastic resin, ABS UL 94 HB, and the output contacts (probes) consist of chrome-plated spheres. The
	The device continually alternates between the positive and negative probes and allows the user to adjust the settings from 0 to 400 microamps for personalized comfort level by pressing the up/down button. Product A requires the use of a conductive derma gel.	device, powered by a 9-volt battery, produces microcurrent that is Discharged through the two fixed, smooth spherical probes. To turn the device on, the thumbwheel is pushed upwards. A Green LED light will Then illuminate, indicating the unit is ready for use. Users then follow the instructions for use. The two probes gently glide over the skin to deliver low-level electrical impulses to strategic locations on the face.
Power Source	One 3.6 V battery	One 8V Battery
Number of output modules	1	1
Number of output channels	1 output channel	1 output channel
Regulated current or regulated Voltage?	Both	Both
Software/Firmware/Microprocessor Control?	Yes	Yes
Automatic Overload Trip?	No	No
Automatic Shut off?	No	No
Patient override control?	Yes	Yes
Indicator Display	Yes	No
Timer range	No Timer	No timer
Type of protection	Type BF	Type BF
Number of output modules	1	1
Number of output channels	1	1
Software/Firmware	No	No
On/off status	No	No
Standards Compliance	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10
Biocompatibility	ISO 10993-5, -10	ISO 10993-5, -10

Source: http://www.accessdata.fda.gov/

From the table above, the performance testing conducted was: electrical safety (per IEC 60601-1), EMC (per 60601-1-2), performance of nerve and muscle stimulators (per IEC 60601-2-10), and requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (per IEC 60601-1-11). Biocompatibility testing was also conducted: cytotoxicity (per ISO 10993-5), and sensitization and irritation (per ISO 10993-10).

Other valuable information in a 510(k) summary

Additional information is available in various sections of the 510(k) Summary. For example, in Section 7 (Clinical Performance Data) of the 510(k) Summary for Product A, the device manufacturer references an 80-person usability and product self-selection study. These types of studies are typically required by the FDA for many home-use devices.

A 510(k) Summary may not identify all tests conducted on the device. 510(k) Summaries for different predicate devices might only reference IEC 60601-1 and IEC 60601-1-2. However, this does not mean additional tests, as well as usability and self-selection studies, were not performed.

If the device contains operating system software that controls program settings and the amount of current administered to the user, risk analysis and software verification and validation are required under product code NFO. Below is a list of related guidance documents that should be evaluated for relevance:

- ISO 14971, Medical devices - application of risk management to medical devices
- IEC 62304, Medical device software - software life cycle processes
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices
- Applying Human Factors and Usability Engineering to Medical Devices
- Design Considerations for Devices Intended for Home Use

This list includes the FDA's guidance documents on human factors and usability engineering, and design considerations for home-use devices. These important design related topics for home use devices must be addressed in the 510(k) submission with supporting data and documentation (i.e., usability and self-selection studies, and user manual) to comply with 21 CFR Part 820.30, Design Controls and 21 CFR Part 801 Labeling.

These extensive testing requirements and other verification and validation activities are often overlooked by many first-time device sponsors. They often lack experience searching FDA databases, making 510(k) submissions, or are not aware of the different types of testing, verification, and validation activities. It is not until the device sponsor receives an Additional Information request from the FDA that they realize it may take much longer than 90 days to clear their device. Also, the process might cost more than they anticipated.

Keep in mind that the 510(k) Summary (or 510(k) Statement) is the only portion of the complete 510(k) submission available in the public domain once a device is cleared.

The difference between a 510(k) Summary and a 510(k) Statement

The 510(k) Summary is written by the manufacturer of the device, not the FDA. However, the FDA is stricter than it used to be regarding required information for the 510(k) Summary of a cleared device. Recently, FDA started to require more detailed technical information in their 510(k) Summaries as a way to help new device sponsors identify those relevant features – including references to performance testing – about the predicate device they chose. This is why 510(k) Summary information for older device clearances may include very little technical information.

For a predicate device with a published 510(k) Statement, rather than a 510(k) Summary, the only information in a 510(k) Statement is the Indications for Use. This is allowed by the FDA, although it carries limitations and conditions. Emergo does not recommend using a predicate device cleared with a 510(k) Statement unless it is the only option available. There will be no other relevant information on that device in the FDA's 510(k) database, which can make it very difficult to demonstrate substantial equivalence, unless one does a side-by-side performance testing against the predicate device.

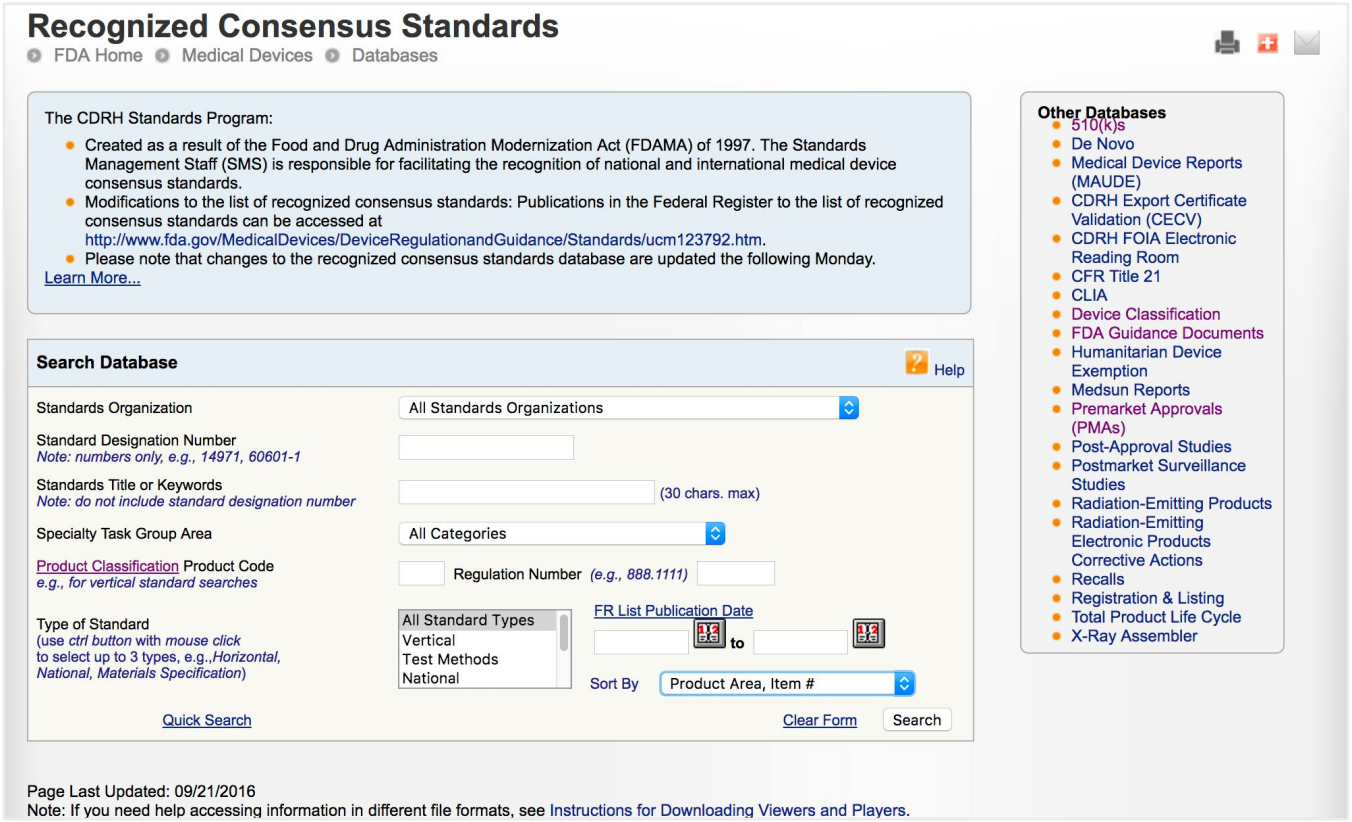
Example 3 – Other search methods using the Recognized Consensus Standards Database

There are other ways to search for a standard in addition to searching by product and regulation number. These different search fields available in the database are shown in **Figure 11**; these include the following options:

- Standards Organization (e.g., ISO, IEC, ASTM, etc.)
- Standards Designation Number (e.g., 14971, 10993, etc.)
- Standards Title or Keywords
- Specialty Task Groups (e.g., sterility, biocompatibility, materials, etc.)
- Type of Standard (e.g., vertical, national, horizontal, etc.)
- Publication Date

Using these search fields can narrow the list of relevant standards for testing your device.

Figure 11 – Different Ways to Search the FDA's Recognized Consensus Standards Database



Source: http://www.accessdata.fda.gov/

How to Use and Understand FDA Databases - Example 3

For example, the FDA may recognize more than one testing standard version, issued by different standards organizations, for the same test. The FDA might impose a transition period for a certain standard, after which they will no longer recognize it. Always check a standard's FDA status before starting expensive testing.

Two common tests in this category address electrical safety and electromagnetic compatibility (EMC). These tests apply to a wide range of medical devices that require a source of electrical power to function.

Entering "electromagnetic" in the "Standards Title or Keywords" field of the FDA's standards database and clicking on the "Search" function in the lower right of the screen extracts the titles of nine different standards as seen in **Figure 12**.

Figure 12 – Extracted Performance Standards for "Electromagnetic"

Recognized Consensus Standards

FDA Home ▸ Medical Devices ▸ Databases

1 to 9 of 9 Results
Standards Title or Keyword: *Electromagnetic*

Results per Page 10

New Search | Export To Excel | Help

Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard	FR Publication Date	Specialty Task Group Area
3-128	AAMI ANSI ISO	14117:2012	Active Implantable Medical Devices -- Electromagnetic Compatibility -- EMC Test Protocols For Implantable Cardiac Pacemakers, Implantable Cardioverter Defibrillators, And Cardiac Resynchronization Devices	07/09/2014	Cardiovascular
3-139	ISO	14117 First Edition 2012-07-15	Active Implantable Medical Devices -- Electromagnetic Compatibility -- EMC Test Protocols For Implantable Cardiac Pacemakers, Implantable Cardioverter Defibrillators, And Cardiac Resynchronization Devices	08/14/2015	Cardiovascular
19-1	IEC	60601-1-2 Edition 3: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests	06/27/2016	General II (ES/EMC)
19-2	AAMI ANSI IEC	60601-1-2:2007/(R)2012	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3)	06/27/2016	General II (ES/EMC)
19-8	IEC	60601-1-2 Edition 4.0 2014-02	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests	06/27/2016	General II (ES/EMC)
19-12	AAMI ANSI IEC	60601-1-2:2014	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests	06/27/2016	General II (ES/EMC)
19-17	ANSI IEEE	C63.18-2014	American National Standard Recommended Practice For An On-Site, Ad Hoc Test Method For Estimating Electromagnetic Immunity Of Medical Devices To Radiated Radio-Frequency (RF) Emissions From RF Transmitters	04/04/2016	General II (ES/EMC)
16-166	ISO	7176-21 Second Edition 2009-04-01	Wheelchairs - Part 21: Requirements And Test Methods For Electromagnetic Compatibility Of Electrically Powered Wheelchairs And Scooters, And Battery Chargers	01/30/2014	Physical Medicine
16-185	ANSI RESNA	WC-2:2009	American National Standard For Wheelchairs - Volume 2, Additional Requirements For Wheelchairs (Including Scooters) With Electrical Systems Section 21: Requirements And Test Methods For Electromagnetic Compatibility Of Electrically Powered Wheelchairs And Motorized Scooters	01/30/2014	Physical Medicine

Source: http://www.accessdata.fda.gov/

Five of the standards listed are actually for specific devices (e.g., pacemakers, defibrillators, wheelchairs and scooters). One standard is related to the measurement of electromagnetic immunity of medical devices to radiated radio-frequency emissions from RF transmitters. Therefore, none of these standards are the relevant general standard for EMC testing.

This leaves four different FDA-recognized versions of the relevant horizontal standard for measuring EMC in medical devices. That standard is 60601-1-2 as seen in **Figure 13**. Clicking on the hyperlink of the versions in **Figure 13** shows an FDA information page related to each standard, as seen for the IEC 60601-1-2 Edition 4.0 version. This link contains all of the related information on that standard, including its FDA recognition number and transition period. To obtain the actual standard, the user must purchase it directly from the issuing standards organization. They are copyrighted by the issuer, and the FDA does not make any standards available to the public.

For example, even if a device sponsor has been selling an electrical-based medical device in Europe for the last 10 years, the FDA may not accept their EMC testing to the second edition of IEC 60601-1-2. For further clarification about how to address a situation like this, see the previously referenced FDA guidance document: *Frequently Asked Questions on Recognition of Consensus Standards*.

Figure 13 – Extracted Performance Standards for "60601-1-2"

Recognized Consensus Standards

FDA Home ▸ Medical Devices ▸ Databases

1 to 4 of 4 Results
Standards Designation Number: 60601-1-2

Results per Page 10

New Search | Export To Excel | Help

Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard	FR Publication Date	Specialty Task Group Area
19-1	IEC	60601-1-2 Edition 3: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests	06/27/2016	General II (ES/EMC)
19-2	AAMI ANSI IEC	60601-1-2:2007/(R)2012	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3)	06/27/2016	General II (ES/EMC)
19-8	IEC	60601-1-2 Edition 4.0 2014-02	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests	06/27/2016	General II (ES/EMC)
19-12	AAMI ANSI IEC	60601-1-2:2014	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests	06/27/2016	General II (ES/EMC)

Source: http://www.accessdata.fda.gov/

Even after looking at all the different FDA databases, you may need to search the predicate manufacturer's website, or those of similar devices, to determine applicable testing requirements. This search method may lead to other valuable information, as some manufacturers place the user manual and/or service manual on their website for the device, which often contains references to conformance standards.

Determining testing requirements for novel devices

For some novel devices, there will be no standardized tests referenced in the FDA databases that adequately test the subject device for its intended use. In these cases, the device sponsor may need to develop their own internal test procedure. The test protocol and report must be included in the 510(k) submission.

Note that the FDA wants data supporting the subject device's safety and effectiveness (SE). Sometimes the only way to demonstrate SE is in the form of comparison or side-by-side testing to the predicate. It is the device sponsor's responsibility to ensure they do the appropriate testing.

However, it may be prudent to discuss any specialized tests with the FDA prior to conducting them, as the FDA may have comments/concerns about the proposed testing. The Pre-Submission Process is the best method for approaching the FDA to discuss proposed testing requirements. Other topics related to the pending 510(k) submission can be addressed through the FDA's Pre-Submission process (see guidance document linked above).

Commonly referenced FDA guidance documents and recognized consensus standards

Table 1 lists some of the common FDA guidance documents and recognized (horizontal) consensus standards that may apply to devices currently under design and development. This table is by no means complete, as other FDA guidance documents and performance standards may apply to your device. Selecting the appropriate FDA guidance documents and performance standards is the device sponsor's responsibility. If in doubt, contact the FDA directly or engage Emergo for assistance.

Table 1 – Commonly Referenced FDA Guidance Documents and Consensus Standards

Guidance Document	Consensus Standard
Use of International Standard ISO-10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process Web Link	ISO 10993-1:2009, Biological Evaluation of Medical devices - Part 1: Evaluation and Testing Within a Risk Management Process
Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile Guidance for Industry and Food and Drug Administration Staff Web Link	ISO 11607-1:2006, Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
	ISO 11607-2:2006, Packaging for Terminally Sterilized Medical Devices -- Part 2: Validation Requirements for Forming, Sealing and Assembly Processes
	ISO 17665-1:2006, Sterilization of Health Care Products - Moist Heat - Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
	ISO 11135:2014, Sterilization of Health-Care Products - Ethylene Oxide - Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
	ISO 11137-1:2006, Sterilization of Health Care Products - Radiation - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices

Table 1 – Commonly Referenced FDA Guidance Documents and Consensus Standards	
Guidance Document	**Consensus Standard**
-	ASTM F1980 – 07:2011, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
-	AAMI / ANSI ES 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices Guidance for Industry and Food and Drug Administration Staff Web Link	IEC 60601-1-2 Ed 4.0, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Web Link	IEC 62304:2006, Medical Device Software - Software Life Cycle Processes
General Principles of Software Validation; Final Guidance for Industry and FDA Staff Web Link	
Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices Web Link	
Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design Web Link	ISO 14971, Medical Devices - Application of Risk Management to Medical Devices
Design Considerations for Devices Intended for Home Use Web Link	

Final Thoughts on Testing Requirements for 510(k) Submissions

Obtaining FDA clearance through the 510(k) process in the 21st century requires some form of device testing, likely to a known standard. It might also require other types of verification and validation activities related to the device's design and performance. These critical items prove the safety and efficacy of the device and, in so doing, demonstrate substantial equivalence to the predicate device. There is simply no way around this. Many companies complain about the FDA's burdensome 510(k) and PMA requirements for medical devices. However, there are very good reasons for them, which are well documented in the news and on the FDA's Warning Letter database.

When bringing a new product to market – especially a medical device, where the stakes are much higher – the chances of achieving commercial success increase when you put more thought into the early stages of planning, design, and development. If you take the time to research all of the testing requirements, FDA guidance documents, and performance standards that apply to your device, your 510(k) submission should move through the FDA's review process with fewer questions.

Two devices submitted under the same product code can have dramatically different 510(k) clearance times if one company understood the FDA testing requirements and the other did not. Understanding the FDA's testing requirements and identifying all the required performance standards, as well as compliance with their applicable guidance requirements, can help you achieve an efficient clearance.

In summary, the key steps to determining the correct FDA guidance documents and performance testing requirements that apply to your device are:

1) Understand the intended use and fundamental scientific technology of your device.

2) Accurately classify your device under the FDA's product classification system.

3) Identify all FDA guidance documents and performance standards, both vertical and horizontal, that apply to the intended use and fundamental scientific technology of your device.

4) Perform an appropriate risk analysis on your device in accordance with ISO 14971 based on the device's product classification, intended use, and fundamental scientific technology.

5) Give early consideration to any potential predicate devices used in your 510(k) submission so you can thoroughly review the testing performed on those devices.

6) Design, develop, and manufacture your device in accordance with 21 CFR Part 820, Quality System Regulation, with particular attention to Part 820.30, Design Controls.

7) Perform all identified testing used in your 510(k) submission on a finished device design, or an accurate prototype of the device that will be placed on the market, and not on a device that is still under development and subject to design changes.

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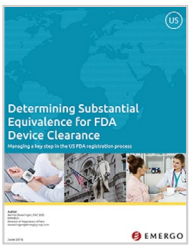

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If you enjoyed this white paper, we know you will like our white paper explaining how to determine substantial equivalence for FDA device clearance. We discuss predicate devices, how the FDA defines substantial equivalence, how to demonstrate substantial equivalence in your 510(k), and much more.

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Stuart Goldman is a Senior Consultant at Emergo with 25 years of experience in the medical device industry. Before joining Emergo in 2006, he spent the first 15 years of his career involved in various quality functions for a leading manufacturer of high-risk cardiovascular implants and instrumentation. He now focuses on medical device regulations for the US and Europe. Stuart's areas of expertise include medical device classification and regulatory strategies and submissions; medical device testing requirements and FDA Warning Letter responses; and QMS audits. Stuart has worked on FDA submissions for a wide range of devices, with a focus on dental, orthopedic, radiological, electrosurgical, general surgical, and personal use products. He has a Bachelor of Science in Materials Science and Engineering from North Carolina State University.