U.S. FDA Medical Device Testing for Premarket Submissions

EMERGO
by UL

Stuart R. Goldman
United States senior consultant
RA/QA ASQ (CMQ/OE, CMDA, CQA)
stuart.goldman@ul.com

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What you will learn in this white paper

Where to locate information on the type of testing you need to conduct for your device

What are the differences between vertical and horizontal standards and guidance documents

What a final finished device and worst-case testing is

Introduction

This white paper will focus on identifying and selecting the appropriate testing for placing medical devices on the market in the U.S.

This white paper assumes a basic understanding of how the U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) classifies and regulates medical devices. For those unfamiliar with this topic, please see the author's accompanying June 2023 white paper, **U.S. FDA Medical Device Classification System**.

Higher-risk medical devices require more regulatory oversight by the FDA, which often includes an applicable premarket submission and substantial testing to various **recognized consensus standards** and conformance with certain **guidance documents** that may be specific to a type of device or applicable to a wide range of devices.

Do all medical devices require the same testing?

No. There are currently over 6,500 product codes to describe the different medical device categories the FDA regulates — covering Class I, Class II, and Class III devices, in addition to "unclassified" (pre-amendment devices for which a classification regulation has not been promulgated) devices and humanitarian device exemption (HDE) devices. Trying to identify what specific testing applies to your device can be fairly simple to determine or a more complicated task that may even require further communication with the FDA before starting your device testing, depending on the device risk and the guidance documents and standards related to that device. The type of testing a medical device should undergo is based on the level of risk the device poses to the intended patient and user(s) — e.g., lay users, healthcare professionals, and caregivers — and is a function of its intended use and technological characteristics.

All medical devices have a certain degree of risk associated with their use, as no device is considered perfectly safe. Just because a device is categorized as Class I and is 510(k) and GMP exempt does not mean that certain testing is not required to commercialize the device, as further discussed in this white paper. To help manage the risk a device poses to a patient and user, the FDA imposes its **Regulatory Controls** — General Controls and Special Controls — that are appropriate to the risk of the device. Class I devices require only general controls. Class II and III devices require general and special controls. Device-specific performance standards and guidance documents help clarify special controls.

Not identifying the correct testing requirements for your device can result in a longer review time at the FDA for a premarket submission, potentially resulting in an Additional Information (AI) request such that you may have to withdraw your submission because you are not able to supply the required test data to the agency in the allotted time.

Also, failure to perform the appropriate testing on a premarket submission exempt (510(k) exempt) device could potentially result in receiving a 483 finding during an FDA inspection of your Quality System, irrespective of not needing to have your device cleared or approved by the FDA before marketing it.

Additionally, devices sold over the counter (OTC) for use by laypersons often require additional testing as compared to the same device if sold by prescription or when used by trained healthcare providers.

Determining testing requirements for your device

As a general rule, many medical devices need to be tested (verified or validated) with one or more of the nine categories of testing listed below based on their intended use and technological characteristics. Device testing and other verification and validation activities conducted under the first eight categories shown below can be found in various FDA guidance documents and recognized consensus standards that are considered ***horizontal*** guidance and standards because they apply to a wide range of devices across all the **Device Classification Panels** within the CDRH.

1. Biocompatibility testing
2. Electrical safety (ES) and electromagnetic compatibility (EMC) testing
3. Sterilization validation
4. Cleaning and reprocessing validation
5. Shelf-life/packaging/shipping validation
6. Software/cybersecurity verification and validation
7. Usability testing
8. Non-clinical performance testing
    a. To a known standard
    b. To a company protocol
9. Clinical testing

Within the category of non-clinical performance testing of medical devices can also be found various FDA guidance documents and recognized consensus standards, but these are usually considered ***vertical*** guidance and standards because they usually apply to very specific types of devices. These guidance documents and standards may be listed on the product classification page for the device as well as in its regulation number.

For devices that are in an established product code, reviewing the publicly available information regarding testing in the 510(k)[1], De Novo[2], PMA[3] or HDE[4] summary can inform total testing requirements. If there is not an established product code, the device is novel, or there is a lack of clarity then a pre-submission (Q-submission) should be considered.

In addition, and as it relates to non-clinical performance testing of devices, there are many product codes that do not have any FDA guidance document or recognized consensus standard assigned to them. In cases like this, it may be appropriate for the company making the device to devise an internal company protocol that adequately tests the device to demonstrate that it meets its specification requirements.

This type of testing should be carried out in accordance with the FDA's related horizontal guidance document, **Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions**. This guidance document describes what sort of information the FDA expects to see in company-developed test protocols and test reports as it relates to performance testing that is not done to a known standard. When developing a company-specific test protocol, a Q-submission is generally recommended to confirm alignment with the FDA.

In addition, you should consider if there are any unique mitigations that are needed based on your device design or indications for use in relationship to appropriately addressing risk, per your risk analysis in alignment with ISO 14971.

Knowing whether your device needs, for example, biocompatibility testing (and what specific types) or electrical safety and electromagnetic compatibility testing, or software verification and validation, etc., needs to be addressed during the design and development stage of your device as described in **21 CFR Part 820.30 Design Controls**. The testing requirements for your device, including verification and validation activities (if applicable), usability testing (if applicable), etc., all need to be identified in the final product specification for your device so that it is clear what testing will be required to bring your device to market in the U.S.

Device testing examples

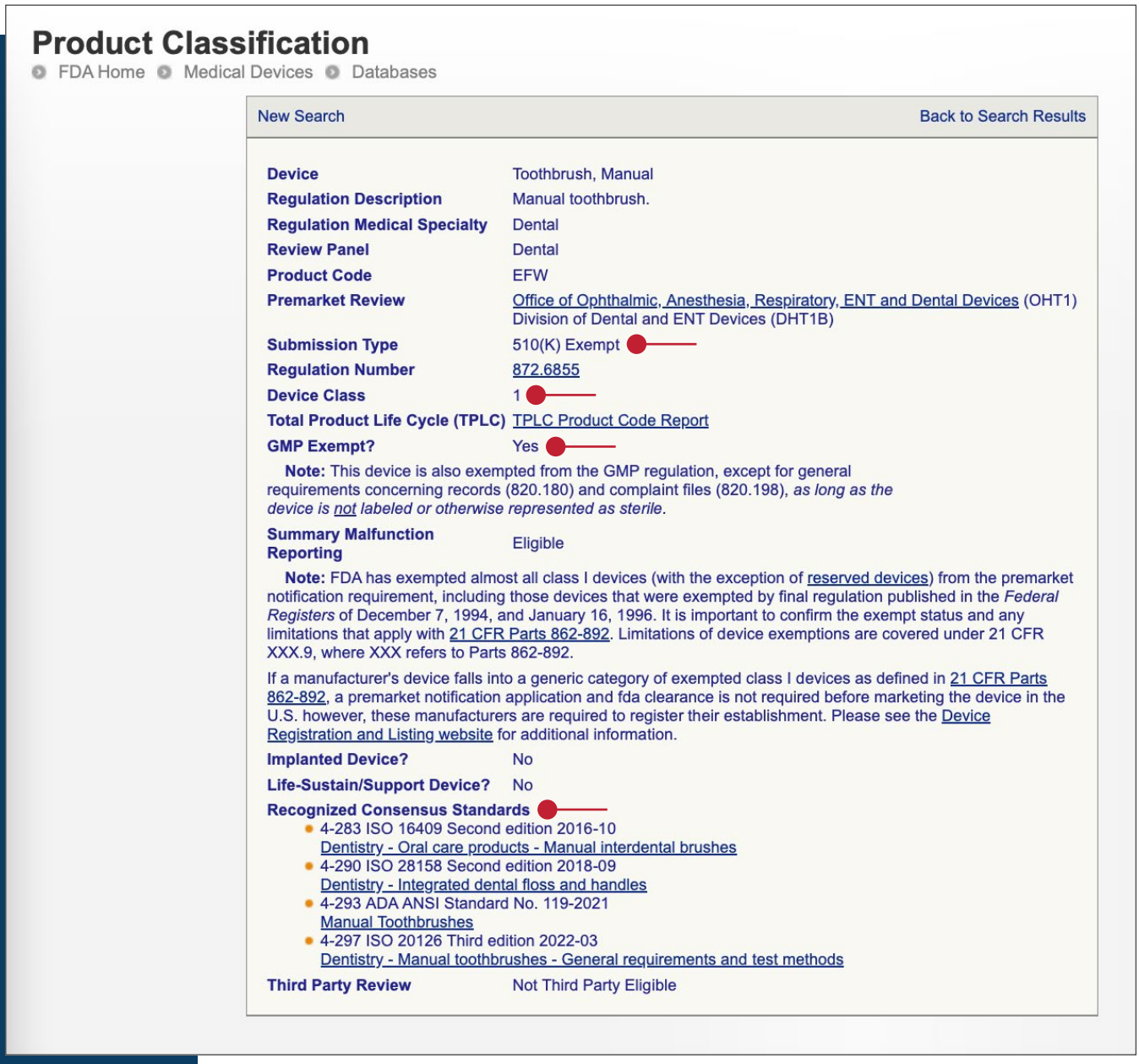
As an initial first step to locate the correct testing requirements for your device, we at Emergo by UL recommend starting with the product classification page for your device, which assumes that you have correctly classified your medical device. In the first example, we use three different dental devices to show some of the differences in the testing information that is available on the different product classification pages, which vary by product code, as seen below.

Example 1 – Testing requirements described on the product classification page

Figures 1-3 show the FDA's product classification pages for the following dental devices:

1. Product code **EFW** (Toothbrush, Manual) – Class I, 510(k) and GMP exempt
2. Product code **NPM** (Bone Grafting Material, Animal Source) – Class II, 510(k)
3. Product code **LZD** (Joint, Temporomandibular, Implant) – Class III, PMA

Figure 1 shows the product classification page for a manual toothbrush under product code EFW. This is a low-risk, Class I 510(k) and GMP-exempt device and manufacturers of them only need to comply with sections §820.180 Records and §820.198 Compliant Files of the FDA's Quality System Regulation (21 CFR Part 820), as long as the toothbrush is not labeled or otherwise represented as sterile. Even for this low-risk device, there are four vertical standards that manufacturers of these devices need to consider for testing, in part or in whole, or have a sound justification for why they do not need to perform these tests. Three of the standards are issued by the International Organization for Standardization (ISO) and the fourth standard is issued jointly by the American National Standards Institute (ANSI) and the American Dental Association (ADA). In addition, as a manual toothbrush makes surface contact with the mucosal membrane of the user for <24 hours of contact duration, the finished device should be tested for cytotoxicity, sensitization and irritation in accordance with the FDA's horizontal biocompatibility guidance document[5] and the applicable parts of ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, especially if a new company is going to be making this device type for the first time.



Product Classification

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Device	Toothbrush, Manual
Regulation Description	Manual toothbrush.
Regulation Medical Specialty	Dental
Review Panel	Dental
Product Code	EFW
Premarket Review	Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Division of Dental and ENT Devices (DHT1B)
Submission Type	510(K) Exempt
Regulation Number	872.6855
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

Recognized Consensus Standards

- 4-283 ISO 16409 Second edition 2016-10
  Dentistry - Oral care products - Manual interdental brushes
- 4-290 ISO 28158 Second edition 2018-09
  Dentistry - Integrated dental floss and handles
- 4-293 ADA ANSI Standard No. 119-2021
  Manual Toothbrushes
- 4-297 ISO 20126 Third edition 2022-03
  Dentistry - Manual toothbrushes - General requirements and test methods

Third Party Review	Not Third Party Eligible

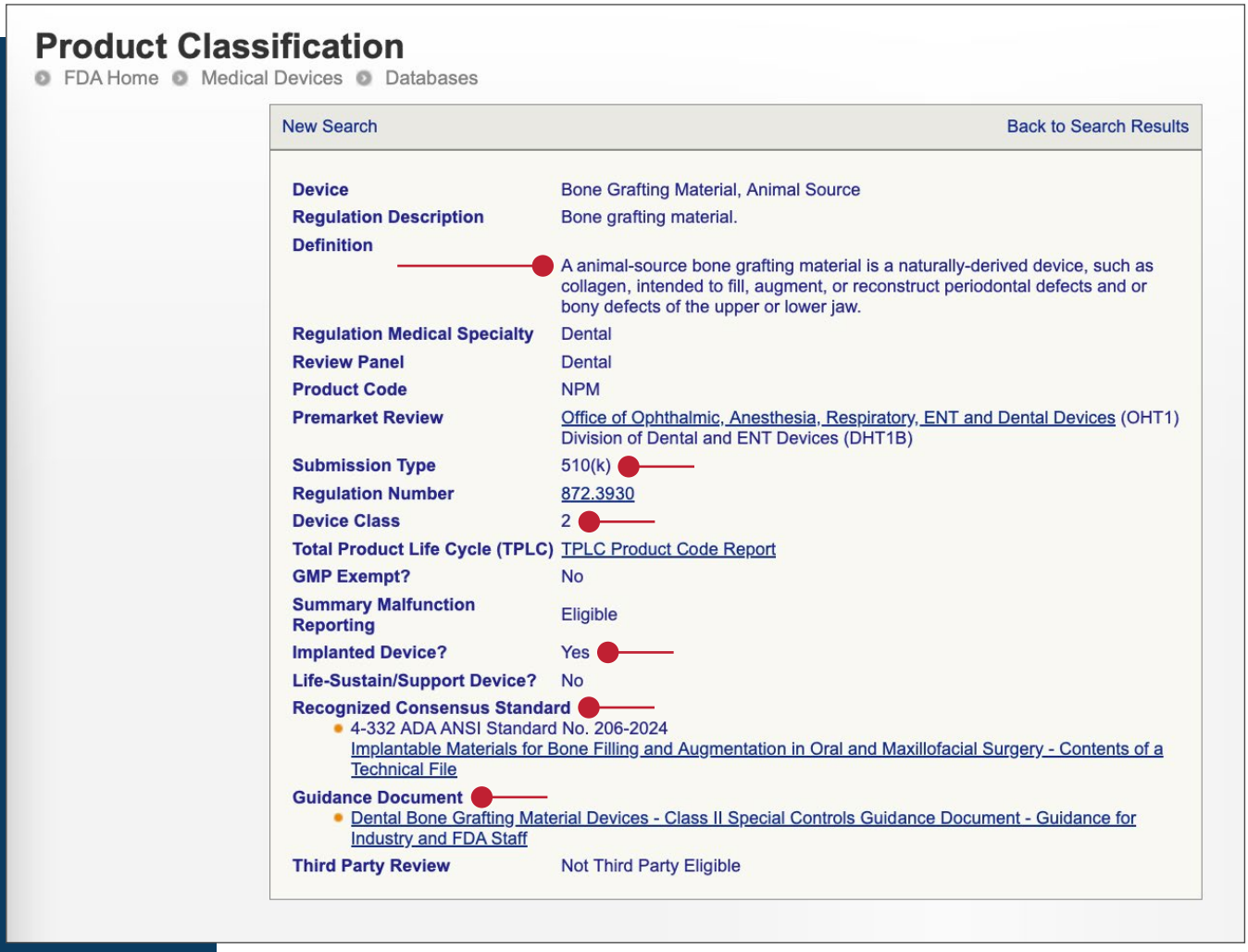
Figure 1 – Product Classification Page for Product Code EFW

Figure 2 shows the product classification page for synthetic bone grafting material derived from an animal source under product code NPM. This is a Class II 510(k) device with a higher level of risk because it is considered to be an implanted device that is ***naturally derived***, typically from collagen, and is intended to fill, augment, or reconstruct periodontal defects and or bony defects of the upper or lower jaw, as described on its product classification page. There is one vertical standard and one FDA special controls guidance document tied to this product code as seen below. Manufacturers of devices under product code NPM need to follow the FDA's recommendations in this guidance document that is also described in its regulation number §**872.3930**[6].

It is within this guidance document that the FDA describes all of the requirements and information that a manufacturer of this device type needs to include in a 510(k) submission to gain clearance. Included in this guidance document are references to other FDA horizontal standards for material characterization testing, biocompatibility testing, sterilization validation, as well as the requirements for chemical composition, physical properties and animal studies for this device type.

Also included in this guidance document are references to other FDA horizonal guidance documents and standards related to the application of risk management for devices utilizing animal tissue and their derivatives; the sourcing, collection and handling of animal tissue and their derivatives; the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents, and recommendations regarding methods for controlling the sourcing of animal tissue with regard to viral pathogens and evaluating the ability of manufacturing methods to remove such pathogens from the final product.

Product code-specific ***special controls*** vertical guidance documents are the best resource that a manufacturer of a device under that product has for making a successful premarket submission to the FDA for their device. However, many device types do not have a special controls guidance document written for them.



Product Classification

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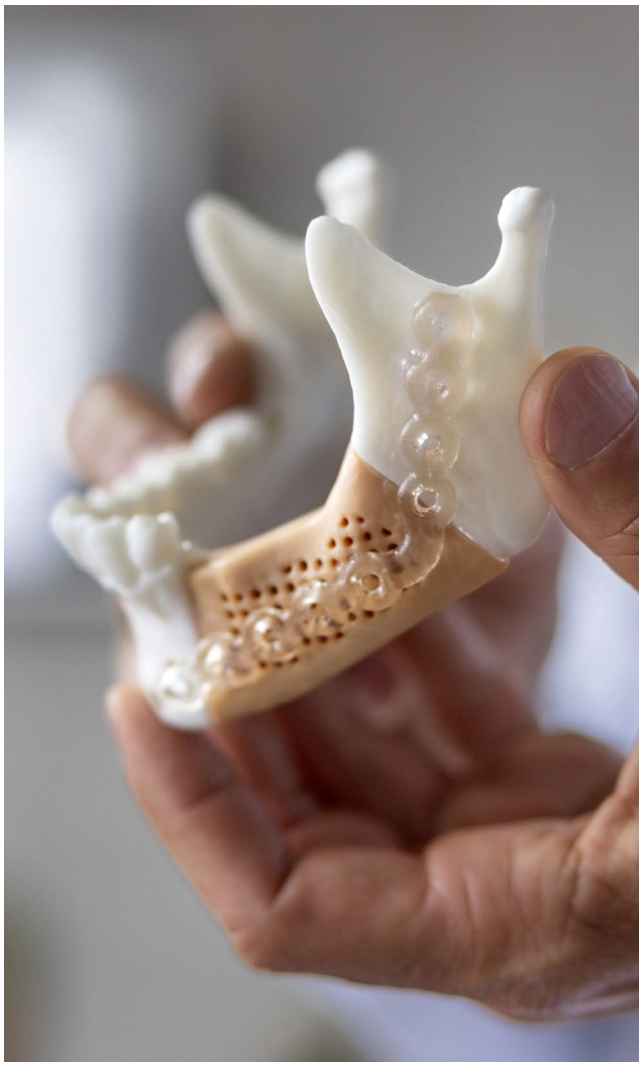
Device	Bone Grafting Material, Animal Source
Regulation Description	Bone grafting material.
Definition	A animal-source bone grafting material is a naturally-derived device, such as collagen, intended to fill, augment, or reconstruct periodontal defects and or bony defects of the upper or lower jaw.
Regulation Medical Specialty	Dental
Review Panel	Dental
Product Code	NPM
Premarket Review	Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Division of Dental and ENT Devices (DHT1B)
Submission Type	510(k)
Regulation Number	872.3930
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	Yes
Life-Sustain/Support Device?	No
Recognized Consensus Standard	• 4-332 ADA ANSI Standard No. 206-2024 Implantable Materials for Bone Filling and Augmentation in Oral and Maxillofacial Surgery - Contents of a Technical File
Guidance Document	• Dental Bone Grafting Material Devices - Class II Special Controls Guidance Document - Guidance for Industry and FDA Staff
Third Party Review	Not Third Party Eligible

Figure 2 – Product Classification Page for Product Code NPM

Figure 3 shows the product classification page for a total temporomandibular joint (TMJ) prosthesis under product code LZD. This is a high-risk Class III PMA device that requires clinical data obtained under an FDA-approved Investigational Device Exemption (IDE)[7] study. There is no special controls guidance document assigned to product code LZD, and the vertical standards listed on the product classification page below for this device only address biocompatibility testing and the properties of the materials used to make the different components of prosthetic TMJ systems. Missing from the list of recognized consensus standards for devices under product code LZD are any standards related to non-clinical performance testing of the device (i.e., wear properties, cyclic fatigue strength, resistance to static loading, etc.), such as the numerous standards that exist for prosthetic hip, knee and shoulder implant systems under various product codes.

The reason non-clinical performance testing standards have not been written for this device type is likely due to the small number of prosthetic TMJ systems that are implanted every year when compared to prosthetic hip, knee and shoulder systems, which have numerous ISO and ASTM standards related to performance testing. A review of one of the two legally marketed devices issued for product code LZD (PMA P020016) shows performance testing was conducted by the manufacturer with their internal tests. Performance testing for this device type would need to be discussed with the FDA under their Q-Submission Program[8] prior to submitting a PMA application. Also referenced in the Summary of Safety and Effectiveness for P020016 were the validation of packaging and shelf-life studies.



Product Classification

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Device	Joint, Temporomandibular, Implant
Regulation Description	Total temporomandibular joint prosthesis.
Definition	Call for PMAs to be filed by 3/30/99 per 63 FR 71746 on 12/30/98 - Indicated for reconstruction of the temporomandibular joint.
Physical State	The device is a ball and socket joint with one side mounted to the jaw and the other side mounted to the head right in front of the ear.
Regulation Medical Specialty	Dental
Review Panel	Dental
Product Code	LZD
Premarket Review	Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Division of Dental and ENT Devices (DHT1B)
Submission Type	PMA
Regulation Number	872.3940
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?	No
Recognized Consensus Standards	

- 4-261 ISO 7405 Third edition 2018-10 Corrected version 2018-12
  Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
- 8-405 ISO 5832-4 Third edition 2014-09-15
  Implants for surgery -- Metallic materials -- Part 4: Cobalt-chromium-molybdenum casting alloy
- 8-406 ISO 5832-11 Second edition 2014-09-15
  Implants for surgery -- Metallic materials -- Part 11: Wrought titanium 6-aluminium 7-niobium alloy
- 8-465 ISO 5832-2 Fourth edition 2018-03
  Implants for surgery - Metallic materials - Part 2: Unalloyed titanium
- 8-500 ISO 5832-12 Third edition 2019-02
  Implants for surgery - Metallic materials - Part 12: Wrought cobalt-chromium-molybdenum alloy
- 8-585 ASTM F1377-21
  Standard Specification for Cobalt-28Chromium-6Molybdenum Powder for Medical Devices (UNS R30075, UNS R31537, and UNS R31538)
- 8-587 ISO 5832-3 Fifth Edition 2021-11
  Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
- 8-594 ISO 5832-6 Third Edition 2022-03
  Implants for surgery -- Metallic materials -- Part 6:Wrought cobalt-nickel-chromium-molybdenum alloy
- 8-595 ISO 5832-5 Fourth Edition 2022-03
  Implants for surgery -- Metallic materials -- Part 5: Wrought cobalt-chromium-tungsten-nickel
- 8-619 ISO 5832-4 Fourth edition 2024-04
  Implants for surgery - Metallic materials - Part 4: Cobalt-chromium-molybdenum casting alloy
- 8-620 ISO 5832-11 Third edition 2024-03
  Implants for surgery - Metallic materials - Part 11: Wrought titanium 6-aluminium 7-niobium alloy

Third Party Review	Not Third Party Eligible

Figure 3 – Product Classification Page for Product Code LZD

Based on the three dental device product codes identified in Example 1, covering Class I, II and III devices, including a Class I device that is 510(k) and GMP exempt, in these three examples, the product classification pages listed vertical standards for some or all of the performance testing needed to market these devices. In the case of product code NPM for the animal-derived bone grafting material, the product classification page did list a vertical standard and FDA special controls guidance document for this device type. The guidance document serves as a guide for what is required to clear one of these devices through a 510(k) premarket notification.

With thousands of product codes to describe all of the different medical devices the FDA regulates, most device types do not have a special controls guidance document, nor do a lot of product classification pages show any vertical standards for that particular product code. In situations like this, the manufacturer of a device making a premarket submission to the FDA will need to determine what specific testing will be required to bring their device to market, which is further discussed in Example 2.

Example 2 – When the product classification page does not reference any standards or guidance documents

There are many product classification pages that do not list any vertical standards or FDA special controls guidance documents on them. In situations like this, a manufacturer making one of these devices should consider what similar competitive devices that have already been authorized by the FDA to try and determine what kind of testing they may need to conduct on their device to gain access to the U.S. market.

The FDA maintains summary information on these legally marketed devices in their publicly accessible 510(k), De Novo and PMA databases (linked in footnotes 1-3), where anyone can look at that information in these submission types to try and glean some insight to the testing requirements for their new device under a certain product code.

In this next example, we use two product codes and submission types. One for an Unclassified (Pre-Amendment) 510(k) device, one for a Class II De Novo device, using product codes KGN and QVS, respectively, as further discussed below. Figures 4-6 show the FDA's product classification pages for the following devices:

1. Product code **KGN** (Wound Dressing With Animal-Derived Material(s)) – Unclassified, 510(k)
2. Product code **QVS** (Breast Implant Suction Retrieval Device) – Class II, De Novo

Figure 4 shows the product classification page for an advanced wound dressing made from animal-derived material under product code KGN. This is an Unclassified Pre-Amendment device that requires 510(k) clearance and is considered a higher-risk device because the product classification page for product code KGN considers this type of a wound dressing to be an implanted device because they are biodegradable and resorbed into the body, where some of these devices act as a scaffold for cellular invasion and capillary growth of the skin to occur. The scaffold is eventually remodeled as the patient's cells rebuild the damaged site of the wound. There are no vertical standards or FDA special controls guidance documents tied to this product code, as seen below. Without this information, a new manufacturer of a device classified under product code KGN should look at 510(k) summaries of recently cleared devices to better understand the type of testing that is required to clear such a device.

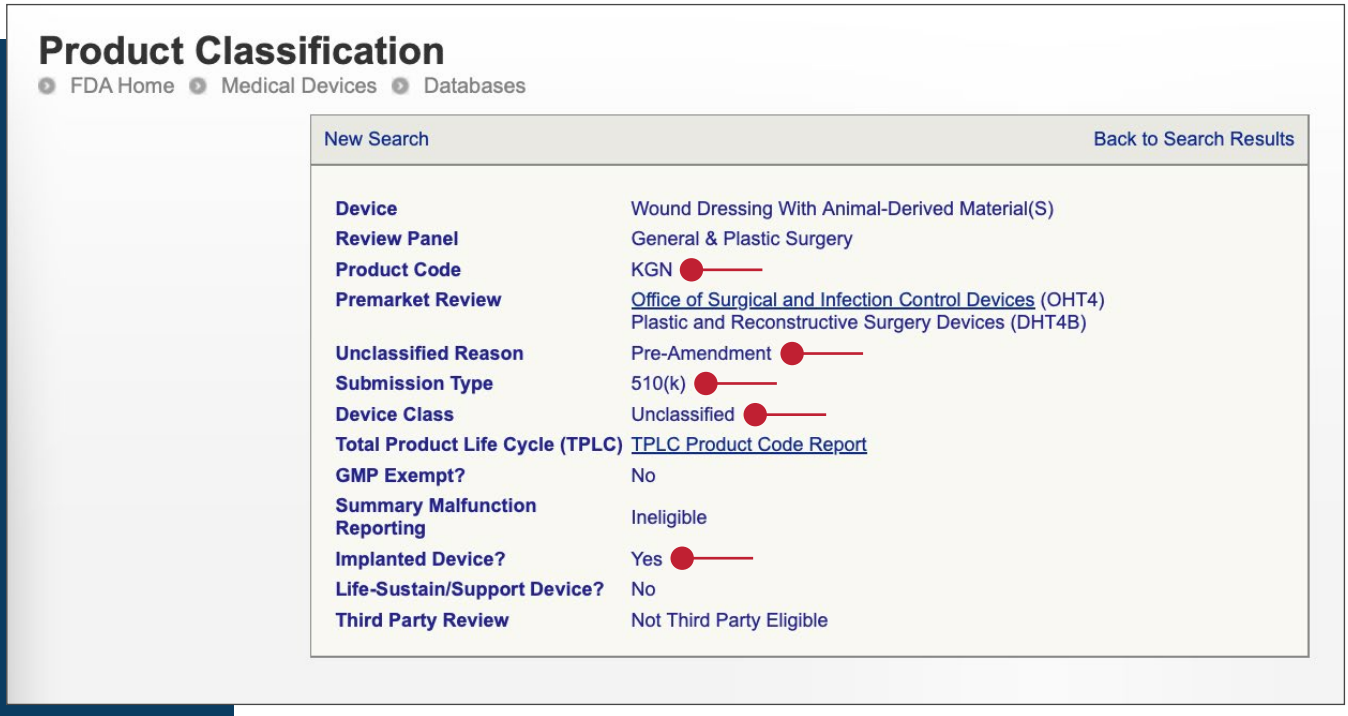


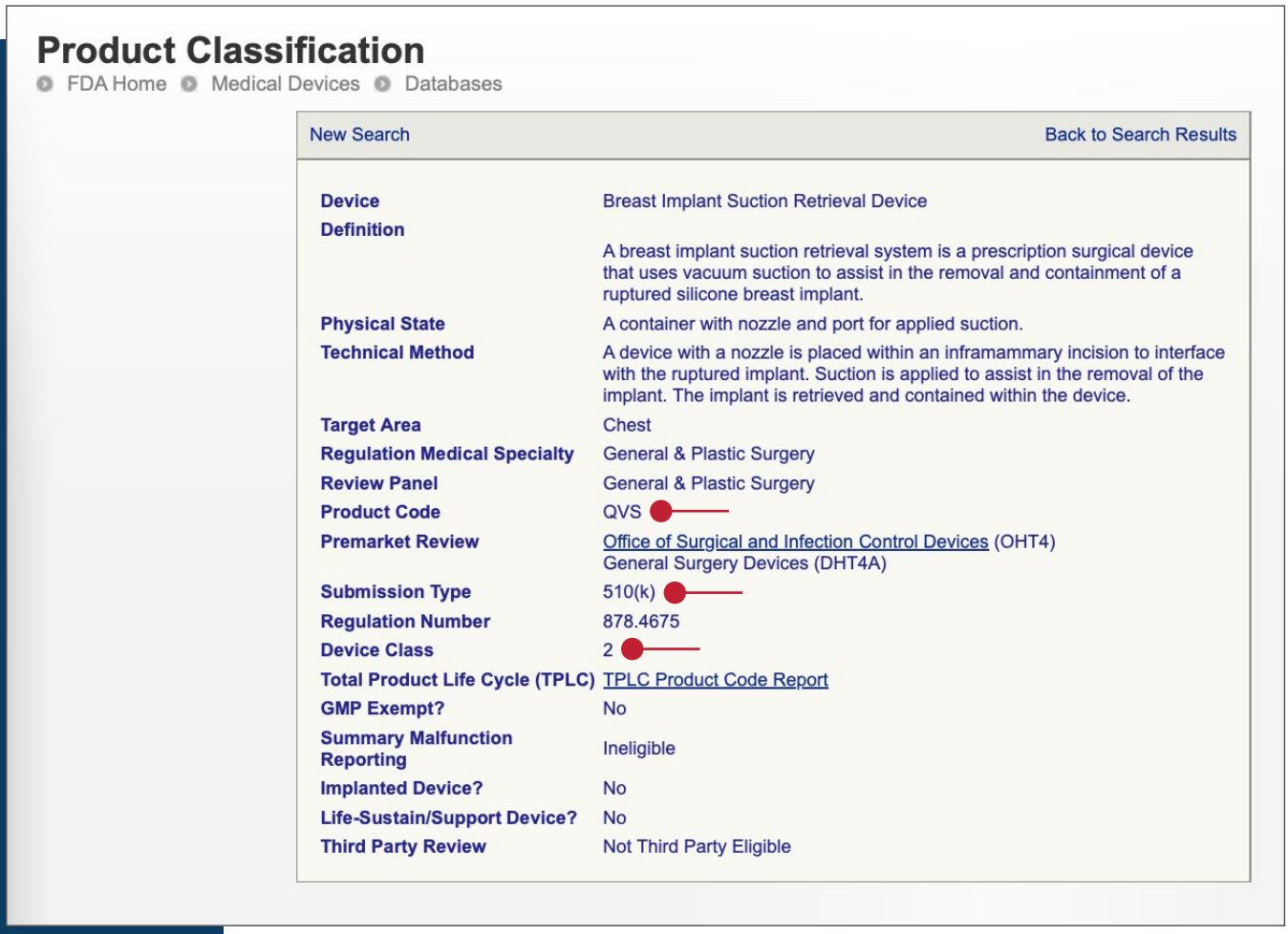
Figure 4 – Product Classification Page for Product Code KGN

A review of a 510(k) Summary for a single device (K191992) cleared under this product code identified the following testing that was performed.

- Animal tissue sourcing and viral inactivation:
  - Done in accordance with FDA Guidance Document – *Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices)*
    - Used in concert with ISO 22442 series of standards, *Medical Devices Utilizing Animal Tissues and their Derivatives* (Part 1-3)
  - Done in accordance with FDA Guidance Document – *Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin*
- Biocompatibility (ISO 10993-1 for: cytotoxicity, implantation, skin sensitization, intracutaneous reactivity, systemic toxicity, toxicological risk assessment and chemical characterization)
- Immunogenicity (human repeat insult patch test)
- Bacterial endotoxin (USP <85>)
- Sterilization (ISO 11135)
- Packaging and shelf life (ISO 11607-1, ASTM F1886)
- Usability (IEC 62366-1)
- Risk analysis (ISO 14971)
- Physical and chemical properties testing
- Non-clinical performance testing

A significant amount of testing was required to clear this particular type of wound dressing, which also included addressing the specific requirements identified in the FDA's two horizontal guidance documents shown above. The non-clinical performance testing was done to internal company protocols established by the device manufacturer.

Figure 5 shows the product classification page for a breast implant suction retrieval device under product code QVS. This is a new Class II device that was granted a De Novo (**DEN220082**) by the FDA in 2023, establishing product code QVS and regulation number 878.4675 for the first time. This device uses vacuum suction to assist in the removal and containment of a ruptured silicone breast implant. There are no vertical standards or an FDA special controls guidance document tied to this product code, as seen below. However, as part of granting a De Novo classification to the manufacturer of this new device type, the FDA and manufacturer had to agree on the special controls that will apply to this new device, as seen in the **Reclassification Order** for this De Novo. These special controls will be codified into the regulation (**878.4675**) once it is written by the FDA.



Product Classification

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Device	Breast Implant Suction Retrieval Device
Definition	A breast implant suction retrieval system is a prescription surgical device that uses vacuum suction to assist in the removal and containment of a ruptured silicone breast implant.
Physical State	A container with nozzle and port for applied suction.
Technical Method	A device with a nozzle is placed within an inframammary incision to interface with the ruptured implant. Suction is applied to assist in the removal of the implant. The implant is retrieved and contained within the device.
Target Area	Chest
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General & Plastic Surgery
Product Code	QVS
Premarket Review	Office of Surgical and Infection Control Devices (OHT4) General Surgery Devices (DHT4A)
Submission Type	510(k)
Regulation Number	878.4675
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

Figure 5 – Product Classification Page for Product Code QVS

For any new company wanting to make a similar device to the one the FDA granted the first De Novo for under product code QVS, they would only need to submit a 510(k) and could use the device referenced in DEN220082 as a predicate device, but they would be required to comply with the special controls established under 878.4675. In addition, the new company would also need to conduct similar testing for their similar device to what is described in the **Decision Summary** for DEN220082.

Final finished device and worst-case testing

Throughout some FDA guidance documents, in particular their **Biocompatibility**, **Non-Clinical Bench Performance Testing** and **Reprocessing Medical Devices in Health Care Settings**, the agency uses the phrases "final finished form" or "final finished design" or "finished device" and "worst case" to describe how devices should be tested for use in premarket submissions as seen in the examples in **Table 1**. This is a particularly important topic and one that a lot of first-time device companies do not thoroughly understand what the ramifications of not submitting a final finished device for testing can have on their premarket submission. The same is true for not submitting their device for testing that represents worst-case use conditions in a clinical setting, which can vary greatly between different types of devices. Note that there may be different worst cases for safety versus effectiveness when there are multiple models of a device, and therefore testing may be required on more than one model. With this in mind, it is important to fully understand what a final finished device and what worst-case testing is, which is further discussed below.

Table 1 – Select FDA Horizontal and Vertical Guidance Document with References to "Final Finished Form or Device," "Finished Device" and "Worst Case" Testing

FDA Guidance Document	Reference made to	
	Final finished form or device/finished device testing	Worst case for device testing
Horizontal Guidance		
Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (2023-Final)	51	6
Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions (2019-Final)	7	4
Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (2015-Final)	0	19
Vertical Guidance		
Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Class II Special Controls Guidance Document for Industry and FDA Staff (2004-Final)	6	1

Final finished device

Per **§ 820.3 Definitions (l)** of 21 CFR Part 820 Quality System Regulation[9], the FDA describes a "finished device" as: (l) *Finished device means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.*

The FDA's **biocompatibility** guidance document describes "final finished form" (see Attachment H: Glossary) as: *Final finished form - a term used for a device or device component that includes all manufacturing processes for the "to- be- marketed" device including packaging and sterilization, if applicable.*

While the FDA's **non-clinical bench performance testing** guidance document describes a "final finished device" (see Page 9, a. Test sample information) as: *Generally, the tested devices should represent the final, finished device that has been subject to all manufacturing processes for the "to be marketed" device (including sterilization, environmental conditioning, simulated transportation, etc.).*

In these slightly different definitions of a finished device, the one constant is that the FDA wants whatever device you submit for testing be exposed to all manufacturing processes, including packaging, transportation, sterilization and shelf-life (if applicable). Ideally, this would amount to taking a packaged and labeled device from your finished goods inventory and submitting it for testing, whether you submit the device to a third-party testing lab or do the testing internally to a company protocol. But this may not always be possible, especially for new device companies just starting out where they may not have any finished goods in inventory sitting on shelves. In cases like this, it is important to have documented evidence that the device you are submitting for testing represents the to-be-marketed device that has gone through all of the FDA's design and production and process controls described in **§ 820.30 Design Controls** and **§ 820.70 Production and Process Controls** of 21 CFR Part 820 Quality System Regulation.

Any changes that are made to the device, including those to the manufacturing materials and methods, once the device has been cleared or approved by the FDA, may require a new premarket submission because of those changes, which need to be considered on a case-by-case basis in accordance with FDA's requirements.[10,11] Therefore, while prototype testing of different design iterations of your device is expected and part of your design and development activities under the FDA's Design Controls regulation, you should wait until your device design has been finalized as that is the device that needs to be submitted for testing, with those test results included in your premarket submission.

We at Emergo by UL also recommend that you include photographs of your device that is being tested in the test report that you intend to submit to the FDA so that it is clear to the reviewer of your submission that the finished device that was submitted for testing is the device that is identified in your premarket submission. If you are submitting a package and labeled device to a testing lab, include pictures of the device, along with pictures of the device removed from the packaging, and also include pictures of the test set-up of your device, if possible. Taking these extra steps will make it easier for the FDA reviewer to confirm that the device that was submitted for testing is the device being discussed in your premarket submission and should help you avoid getting any questions from the FDA about what was tested.

Worst-case device testing

While the definition of a finished device is fairly easy to understand, when it comes to the topic of determining the worst-case model of your device for testing, this can often be a more challenging exercise, especially if there is no FDA-recognized consensus standard or special controls guidance document for your device's product code. For example, the endosseous dental implant special controls guidance document referenced in Table 1 specifically describes what the FDA wants to see as it relates to non-clinical testing in Sections 8-11 of that guidance document. Also, when looking in the 510(k), De Novo and PMA databases to determine what sort of testing similar devices to yours may have gone through, Emergo recommends looking at devices that have recently been cleared, granted or approved by the FDA as those devices often have more useful testing information in them as opposed to older premarket submissions as well as more accurately reflecting the FDA's current thinking on a topic.

Worst-case testing for a particular device type can be influenced by many factors across the different categories of non-clinical testing described in this white paper and needs to be assessed on a case-by-case basis. If there remains a lack of clarity, we at Emergo recommend discussing your non-clinical testing plan with the FDA to gain their feedback and alignment on your proposed testing to verify that you have adequately identified all of the testing requirements for your device. The best way to do this is through the FDA's Q-submission Program previously discussed above. If you need to develop unique testing for your device, we at Emergo also recommend including a draft of your test protocol for the FDA's review. It should be noted that the FDA will not comment on your actual test results under their Q-submission Program, as they will only do that when reviewing your premarket submission.

Summary

We at Emergo have discussed some of the challenges related to identifying relevant information on medical device testing for your particular device, using various examples to better help you locate this important information. While it can often be fairly easy to locate this testing information, there are times when trying to locate testing information for a device can be challenging. There will also be times when you may need to discuss your proposed device testing with the FDA before making the actual premarket submission for your device.

In summary, the key steps to determining the correct testing requirements for your device are:

- Understand its intended use and technology.
- Check that you have identified its correct product code.
- Perform an appropriate risk analysis in accordance with ISO 14971 such that you have identified all associated risks and mitigation measures for those risks.
- Identify all FDA-related guidance documents and performance standards, both vertical and horizontal, that apply to your device.
- Review recent 510(k), De Novo and PMA submissions to see what kind of testing similar devices to yours underwent under the same product code.
- Establish a test plan for your device that:
  - Identifies every test needed
  - Identifies every FDA-recognized consensus standard for the identified test and/or
  - Identifies every company-written test protocol for the identified test
  - Identify all third-party testing labs to complete your testing if the testing is not done internally to a company-written test protocol

End Notes

1. 510(k) Premarket Notification (fda.gov)
2. Device Classification Under Section 513(f)(2)(De Novo) (fda.gov)
3. Premarket Approval (PMA) (fda.gov)
4. Humanitarian Device Exemption (HDE) (fda.gov)
5. Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" - Guidance for Industry and Food and Drug Administration Staff (fda.gov)
6. Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices) - Guidance for Industry and Food and Drug Administration Staff (fda.gov)
7. Investigational Device Exemption (IDE) | FDA
8. Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Draft Guidance for Industry and Food and Drug Administration Staff (fda.gov)
9. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820
10. https://www.fda.gov/media/99812/download
11. https://www.fda.gov/media/99785/download

About the author

Stuart R. Goldman has over thirty years of combined RA/QA experience in medical devices, including fifteen years in the industry working on high-risk Class III/II implantable devices. At Emergo by UL, Goldman 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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