Fundamentals of Digital Health Regulation: Successfully Navigating Through FDA

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FDLI

Agenda

- Device Classification
- Premarket Pathways
- Working with FDA
- Current Agency Initiatives At a Glance
- Other Considerations
- Case Study/Example

Device Classification

- FDA classifies devices according to risk
- There are specific classification regulations for types of devices
- The classification regulation indicates whether the device is Class I, II, or III
- How do I know how my device is classified?

1. Search the FDA database using terms that describe your product
2. How are your competitors' products classified? Search the FDA databases for your competitor products
3. How are similar products classified?
4. Document the product classification determination in a memo to the regulatory file

How Do I Know How My Device Is Classified?

Product Classification

FDA Home › Medical Devices › Databases

1 to 45 of 45 results
software

Results per page 100

New Search Export to Excel Help

Product Code	Device		Regulation Number	Device Class
PHV	Continuous Glucose Monitor Retrospective Data Analysis Software		862.2120	1
QBZ	Automated Platform Consisting Of Software And Inst ...	Pipetting And Diluting System For Clinic...	862.2750	1
PTB	Ataxiagraph With Interpretive Software	Ataxiagraph	882.1030	1
OUM	Adaptometer (Biophotometer), Software-Based Data A ...	Adaptometer (Biophotometer)	886.1050	1
PJA	Coronary Vascular Physiologic Simulation Software	Coronary Vascular Physiologic Simulation...	870.1415	2
PMJ	Cpr Aid Feedback Device (No Software)	Cardiopulmonary Resuscitation (CPR) Aid	870.5210	2
QDA	Electrocardiograph Software For Over-The-Counter Use		870.2345	2
QDB	Photoplethysmograph Analysis Software For Over-The-Counter Use		870.2790	2
QEK	Angiographic Coronary Vascular Physiologic Simulat ...	Coronary Vascular Physiologic Simulation...	870.1415	2
PZO	Software For Visualization Of Vascular Anatomy And ...	Picture Archiving And Communications Sys...	892.2050	2
PNN	Orthodontic Software	Orthodontic Plastic Bracket	872.5470	2

Device Classification – Class I Devices

- Subject to general controls
- Most exempt from 510(k) premarket notification
- Many Class I devices exempt from GMP requirements, but **not** software devices

Example

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 880 -- GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart G--General Hospital and Personal Use Miscellaneous Devices

Sec. 880.6310 Medical device data system.

(a) *Identification.* (1) A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

(i) The electronic transfer of medical device data;

(ii) The electronic storage of medical device data;

(iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or

(iv) The electronic display of medical device data.

(2) An MDDS may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol. This identification does not include devices intended to be used in connection with active patient monitoring.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 880.9.

[76 FR 8649, Feb. 15, 2011]

Device Classification – Example Class I Device

New Search | Help | More About 21CFR

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2019]
[CITE: 21CFR882.1030]

See Related Information

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 882 -- NEUROLOGICAL DEVICES

Subpart B--Neurological Diagnostic Devices

Sec. 882.1030 Ataxiagraph.

(a) *Identification.* An ataxiagraph is a device used to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed.

(b) *Classification.* Class I (general controls).

[44 FR 51730, Sept. 4, 1979, as amended at 66 FR 46952, Sept. 10, 2001]

Device	Ataxiagraph With Interpretive Software
Regulation Description	Ataxiagraph.
Definition	Device used to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed and provides interpretation or clinical implication of the measurement.
Physical State	Sensors applied to the body and software to analyze and interpret the signals.
Technical Method	Sensors applied to the body and software to analyze and interpret the signals.
Target Area	Trunk and extremities
Regulation Medical Specialty	Neurology
Review Panel	Neurology
Product Code	PTB
Premarket Review	Neurological and Physical Medicine Devices (OHT5) Neurosurgical, Neurointerventional and Neurodiagnostic Devices (DHT5A)
Submission Type	510(k)
Regulation Number	882.1030
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Device Classification – Class II Devices

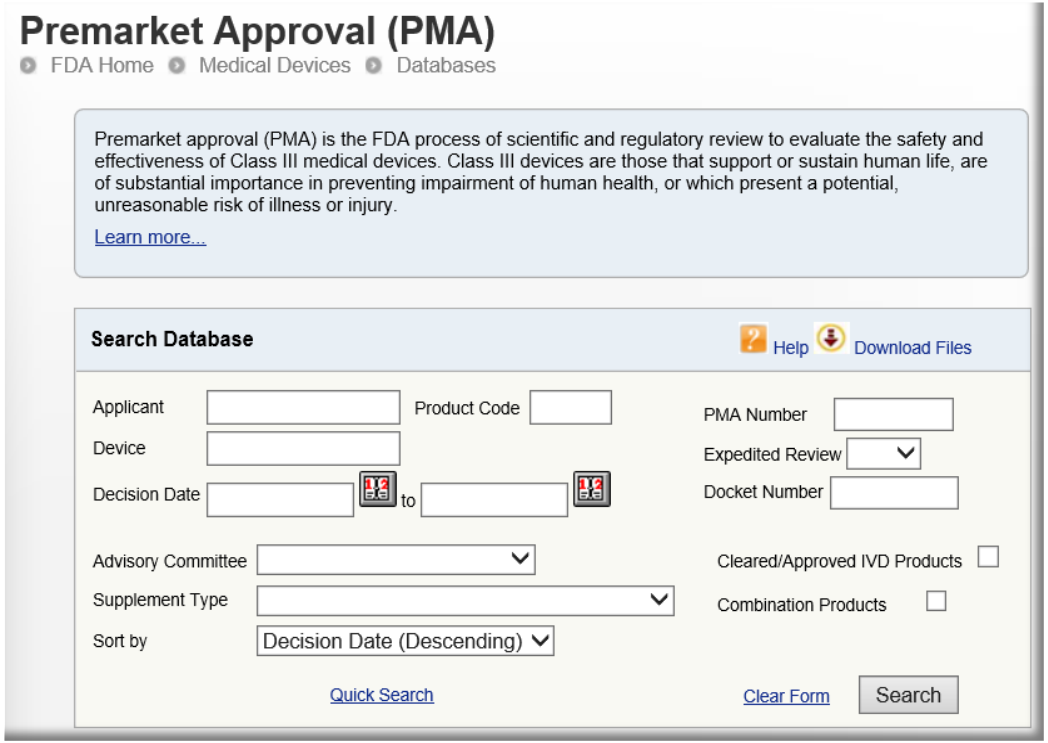
- General controls PLUS special controls
- Special controls can include:
  - Performance standards
  - Special labeling requirements
  - Premarket, postmarket data requirements
  - Guidance documents
- Most Class II devices require 510(k) premarket notification before they may be marketed

Device Classification – Example Class II Device

Device	Mobile / Tablet Software Application To Control Settings Of Surgical And Endoscopic Camera
Regulation Description	Endoscope and accessories.
Definition	Device is intended for wireless control of settings for surgical or endoscopic camera control unit and patient information system.
Physical State	Software only device without any physical part
Technical Method	A software device that runs on a mobile or tablet device and wirelessly connects with compatible surgical or endoscopic camera control unit and patient information system.
Target Area	Surgical sites within articular cavities, body cavities, hollow organs, canals and the thoracic cavity to obtain pictures or videos of these areas.
Regulation Medical Specialty	Gastroenterology/Urology
Review Panel	General & Plastic Surgery
Product Code	QGY
Premarket Review	Surgical and Infection Control Devices (OHT4) General Surgery Devices (DHT4A)
Submission Type	510(k)
Regulation Number	876.1500
Device Class	2

Device Classification – Class III Devices

- **FDA approval before commercial distribution**
- **Devices that:**
  - Support human life;
  - Are of substantial importance in preventing impairment of human health; or
  - Present a potential, unreasonable risk of illness or injury



Device Classification – Example Class III Device

Device	Optical Diagnostic Device For Melanoma Detection
Definition	Intended in the detection of melanoma and high grade lesions among atypical lesions in order to rule-out melanoma.
Physical State	Optical radiation.
Technical Method	Use of visible and infrared optical radiation to generate images of targeted atypical lesions.
Target Area	Atypical pigmented lesions
Review Panel	General & Plastic Surgery
Product Code	OYD
Premarket Review	Surgical and Infection Control Devices (OHT4) General Surgery Devices (DHT4A)
Submission Type	PMA
Device Class	3
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

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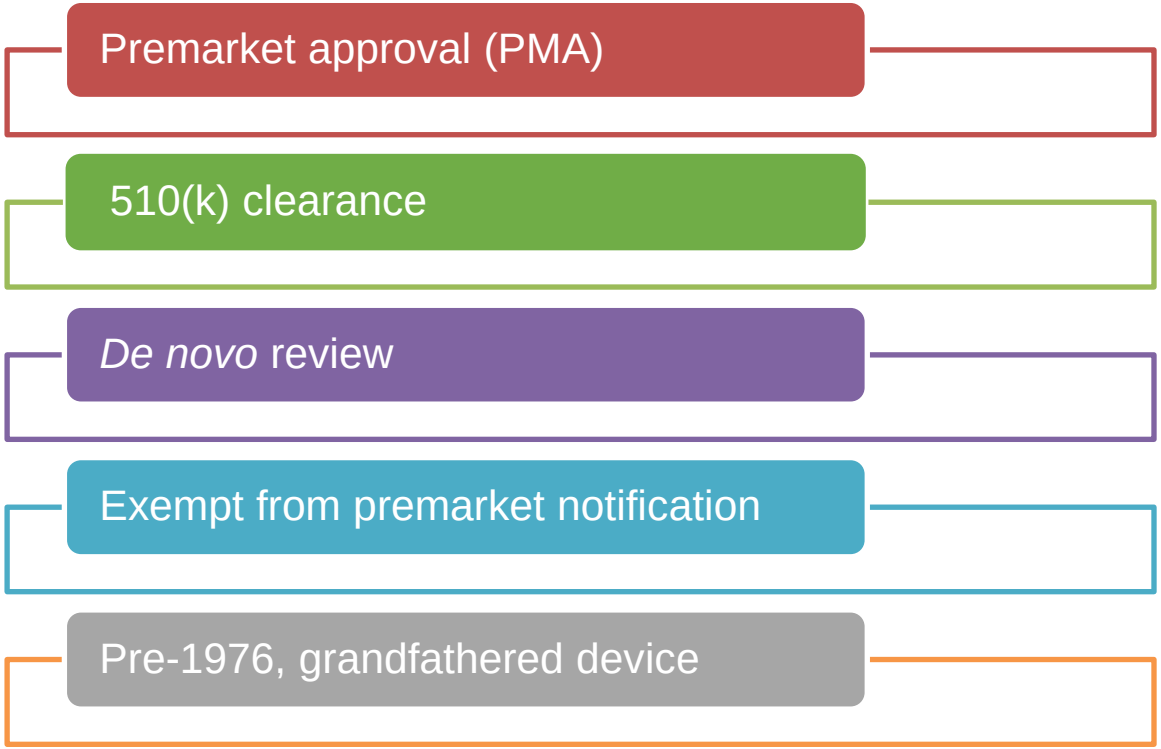
Premarket Pathways



PMA

- By default, FDA classifies devices into the highest risk (i.e., Class III requiring PMA) if there is no existing classification regulation
- FDA assesses a PMA to determine whether the information provided by the sponsor provides a “reasonable assurance of safety and effectiveness”
- Applicant must provide “valid scientific evidence” of safety and effectiveness
  - Well-controlled investigations, partially controlled studies, studies and objective trials without matched controls
  - Well-documented case histories conducted by qualified experts
  - Reports of significant human experience with a marketed device
- Clinical data
- Filing fee: $365,657 (FY 2021 user fee)

PMA Supplements

- PMA supplement is required for a change affecting the safety or effectiveness of an approved device

PMA Supplement Type	Description
Prior approval (180 days)	• For significant changes that affect the safety and effectiveness of the device • In-depth review and approval by FDA required before implementation of the change
30-Day Notice	• Used for modifications to manufacturing procedures that affect the safety and effectiveness of the device • Change may be made 30 days after FDA receives the notice, unless FDA informs the PMA holder that the notice is not adequate
Changes Being Effected	• Can implement after FDA acknowledges receipt that submission qualifies for “CBE” supplement
Annual Report	• Certain changes not reported in PMA supplement

510(k) Clearance

- A 510(k) notification leads to “clearance,” not approval, of the device
- Notification must be submitted to FDA 90 days before introducing device into commercial distribution
- Must wait for FDA to issue order that device is “substantially equivalent” to a predicate device
  - A predicate device is a device that was first marketed before May 28, 1976 or was marketed after May 28, 1976 but was found to substantially equivalent to a pre-1976 device

- Good FDA resource on 510(k) submissions: https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k

Substantial Equivalence

- A device is substantially equivalent if, in comparison to a predicate it:
  - has the same intended use as the predicate; **and**
  - has the same technological characteristics as the predicate;

  OR
  - has the same intended use as the predicate; **and**
  - has different technological characteristics and does not raise different questions of safety and effectiveness; **and**
  - the information submitted to FDA demonstrates that the device is as safe and effective as the legally marketed device.
- Filing fee: $12,432 (2021 user fee)

Device Modifications

- Certain modifications to cleared devices require a new 510(k)
  - Reference FDA flow charts
- Must establish that the device has the same intended use as a legally marketed predicate device and
  - Has the same technological characteristics as the predicate device, or
  - Has different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device, and does not raise different questions of safety and effectiveness than the predicate device

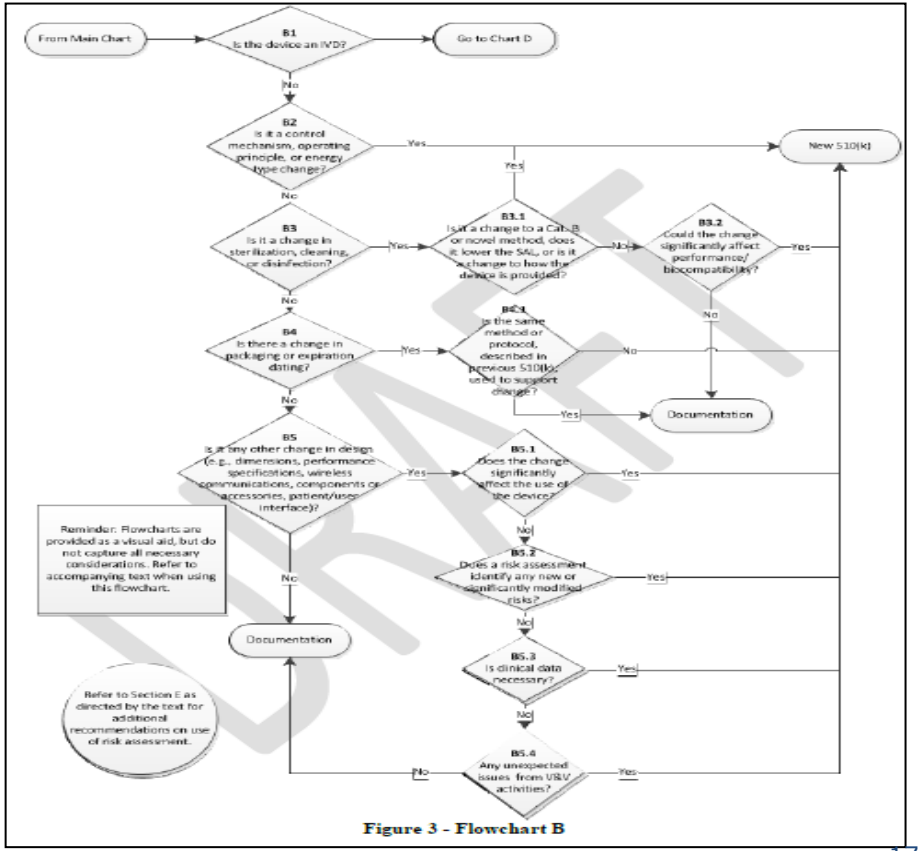
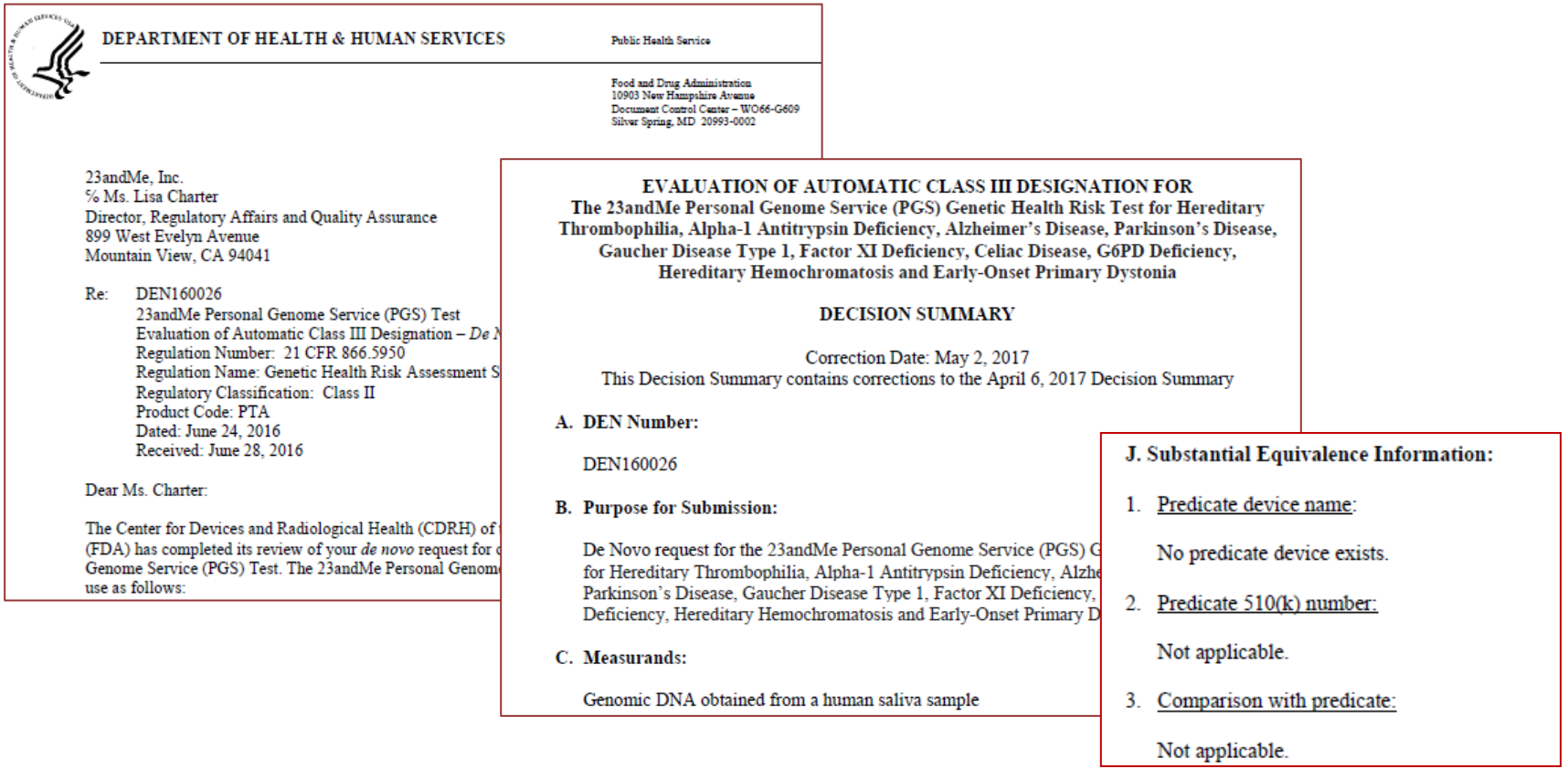


Figure 3 - Flowchart B

De Novo Review

- Suited to low-risk, novel devices – like digital health products – where there is no predicate device
- Permits FDA to "down classify" a novel device from the default class III designation, if:
  - The device is low to moderate risk and
  - General controls, in combination with special controls (if required), are sufficient to provide a reasonable assurance of safety and effectiveness
- Devices that are classified through the *de novo* process may be used as predicates for future 510(k) submissions
- Filing fee: $109,697 (2021 user fee)

De Novo Example



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

23andMe, Inc.
% Ms. Lisa Charter
Director, Regulatory Affairs and Quality Assurance
899 West Evelyn Avenue
Mountain View, CA 94041

Re: DEN160026
23andMe Personal Genome Service (PGS) Test
Evaluation of Automatic Class III Designation – *De N*
Regulation Number: 21 CFR 866.5950
Regulation Name: Genetic Health Risk Assessment S
Regulatory Classification: Class II
Product Code: PTA
Dated: June 24, 2016
Received: June 28, 2016

Dear Ms. Charter:

The Center for Devices and Radiological Health (CDRH) of
(FDA) has completed its review of your *de novo* request for
Genome Service (PGS) Test. The 23andMe Personal Genom
use as follows:

EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR
The 23andMe Personal Genome Service (PGS) Genetic Health Risk Test for Hereditary Thrombophilia, Alpha-1 Antitrypsin Deficiency, Alzheimer's Disease, Parkinson's Disease, Gaucher Disease Type 1, Factor XI Deficiency, Celiac Disease, G6PD Deficiency, Hereditary Hemochromatosis and Early-Onset Primary Dystonia

DECISION SUMMARY

Correction Date: May 2, 2017
This Decision Summary contains corrections to the April 6, 2017 Decision Summary

A. DEN Number:

DEN160026

B. Purpose for Submission:

De Novo request for the 23andMe Personal Genome Service (PGS) G
for Hereditary Thrombophilia, Alpha-1 Antitrypsin Deficiency, Alzhe
Parkinson's Disease, Gaucher Disease Type 1, Factor XI Deficiency,
Deficiency, Hereditary Hemochromatosis and Early-Onset Primary D

C. Measurands:

Genomic DNA obtained from a human saliva sample

J. Substantial Equivalence Information:

1. Predicate device name:

   No predicate device exists.

2. Predicate 510(k) number:

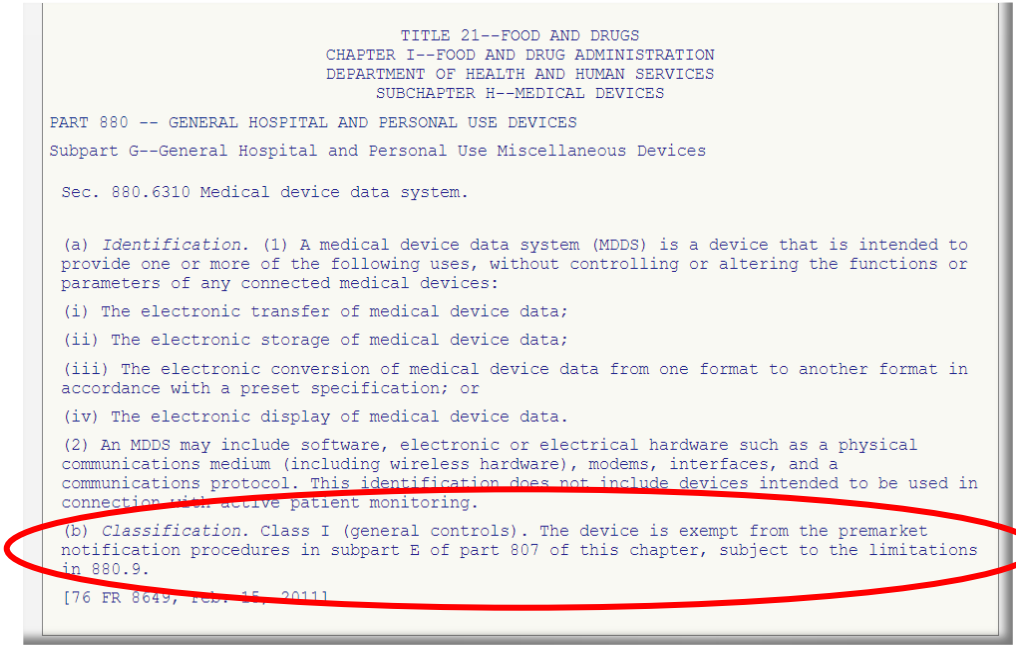
   Not applicable.

3. Comparison with predicate:

   Not applicable.

Exempt Devices

- Exempt devices do not require any premarket submission
- But, general controls still apply:
  - Facility registration
  - Product listing
  - Recalls, corrections, removals
  - MDRs
  - Labeling
  - Adulteration and misbranding provisions
- Note the “8XX.9” limitation



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[76 FR 8649, FEB. 15, 2011]

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Q-Sub Process

- Informal way to engage FDA, prior to submitting an application
  - Voluntary
- Opportunity to obtain FDA feedback on specific questions
  - New technology, or where classification is unclear
  - Proposal for performance testing, planned clinical studies
- Requires a written package
- Requestors may request a face-to-face meeting or teleconference (pre-pandemic)
- FDA review team provides written feedback in 70 days (pre-pandemic)

Benefits:

- Plan studies with acceptable endpoints
- Potentially shorter application review time
- Potentially smoother review process

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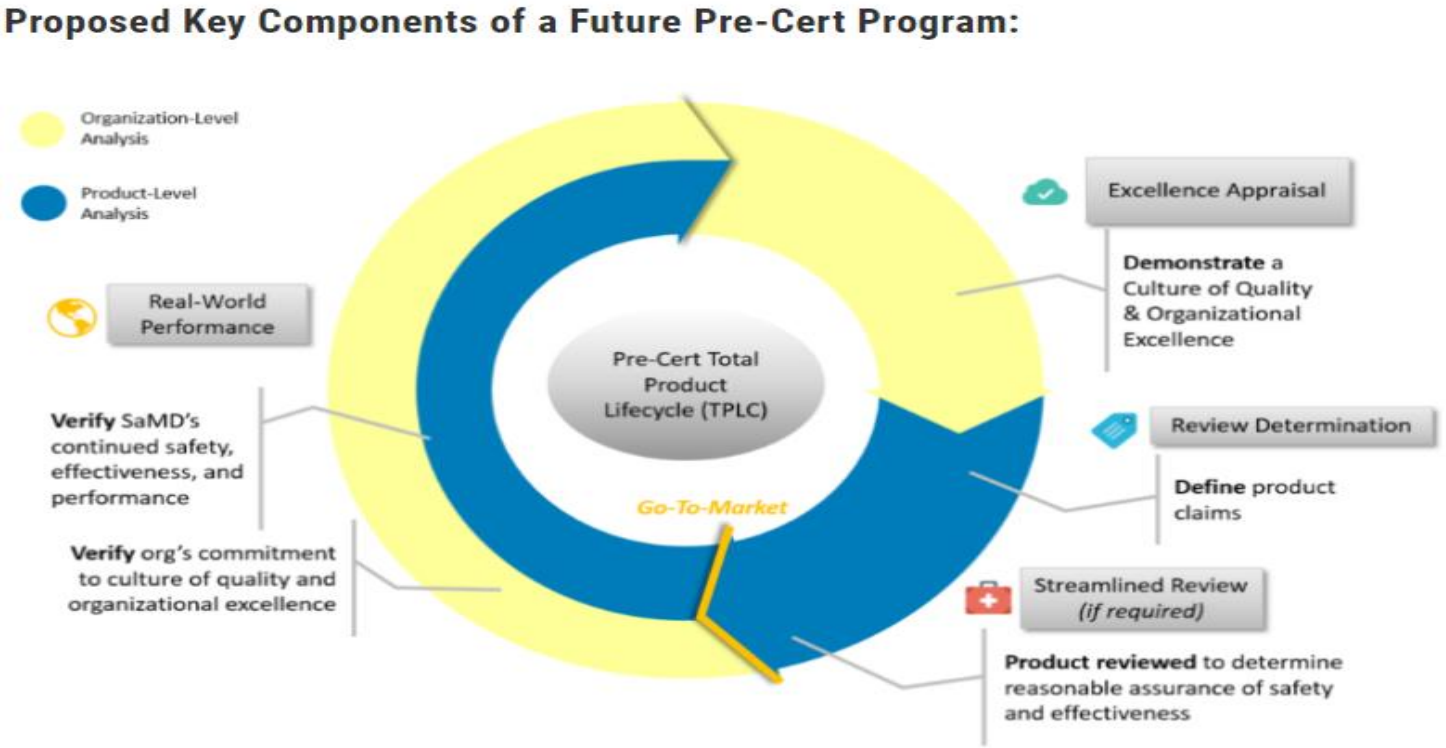
CDRH Management Directory by Organization | FDA

Division of Digital Health		
Division Director	Bakul Patel	301-796-5528
Deputy Division Director	Brendan O'Leary	301-796-5528
Chief Medical Officer for Digital Health Center For Excellence	Matthew Diamond, M.D.,Ph.D	301-796-5386
Assistant Director for Digital Health Policy Leadership and Development	Sonja Fulmer	240-402-5979
Assistant Director for Emerging Digital Health Technology Assessment and Strategy	Vacant	
Supervisor for Digital Health Center of Excellence	Anindita Saha	301-796-2537

Current Initiatives

1. 21st Century Cures Act (2016)
   - Exempted certain software from the definition of “device” (*e.g.*, clinical decision support or CDS)
   - FDA has updated guidance to reflect the new law
2. Cybersecurity has become a more significant consideration during review
3. AI and machine learning – still figuring it out
4. Software pre-certification program
   - Streamlined model for software developers with demonstrated quality culture

Current Agency Initiatives – Pre-Cert Program



Source: https://www.fda.gov/medical-devices/digital-health/digital-health-software-precertification-pre-cert-program#program

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Investigational Device Exemption

- If a firm is studying a digital health product, it is important to consider whether IDE regulatory requirements might apply (21 CFR Part 812)
- “Significant risk” – IDE approval
- “Nonsignificant risk – IRB approval
- IDE regulations exempt certain studies (e.g., consumer preference)

User Fees / Timelines

- User fees for various filings adjust annually – available on FDA's web site
  - REMEMBER: Small business exemption can take up to 6 weeks to obtain
  - Don't forget to apply well in advance of filing!
  - Must be renewed every fiscal year (10/1)

User Fees / Timelines

- FDA review cycle timelines
  - 510(k) – 90 days
  - De novo – 150 days
  - PMA – 180 days

Combination Product Definition

- Definition of combination product, 21 CFR 3.2(e)
  - Two or more regulated components
    - Combined in a single physical or chemical entity or
    - Placed in a single package or unit

Combination Product Definition

- Definition of combination product
  - A single component packaged separately and labeled for use with an approved “individually specified” component
    - Where both are required to achieve effect and
    - Labeling of approved product would need to be changed

Primary Mode of Action

- Mode of action is means by which product achieves a therapeutic effect or action (21 CFR 3.2(k))
- Primary mode of action is the single mode of action of a combination product that provides the most important therapeutic action (i.e., expected to make the greatest contribution to the overall intended therapeutic effect of the combination product) (21 CFR 3.2(m))

Primary Mode of Action

- If no primary mode of action can be determined, primary jurisdiction is assigned to Center that regulates other combination products that present similar questions of safety and effectiveness
- If no other combination product presents similar questions of safety and effectiveness, then assignment will be to Center with the most expertise related to the most significant safety and effectiveness questions presented by the combination product

Unique Considerations for Pharma

- Software can be:
  - companion product
  - compliance aid
- First step is to analyze classification:
  - Is it a combination product or a stand-alone device? Not regulated by FDA under Cures?
  - *Companion diagnostic* – "information that is essential for the safe and effective use of a corresponding drug or biological product" –
    - Typically requires separate device approval, usually a PMA (clinical studies in drug center)

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Wireless Connection to Tablets / Phones

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181672

Device Name
SureTouch Mobile Pressure Mapping System

Indications for Use *(Describe)*
The SureTouch Mobile Pressure Mapping System is intended to p
documenting palpable breast lesions identified during a clinical b
Mapping System is intended for use by a qualified healthcare pro

Predicate Device: BreastView Visual Mapping System (DEN020001). This predicate device has not been subject to any design related recalls.

Device Description:

The SureTouch Mobile Pressure Mapping System ("SureTouch") is a computer-based device that produces a pressure map, called a tactile image, of specific areas of the breast as an aid to document lesions detected during a clinical breast exam. SureTouch utilizes a rechargeable, battery-powered hand-held wand (sensor unit) that incorporates a 30 x 40 mm array of pressure sensing elements to collect tactile data as the device is moved across the breast. Data collected using the wand are wirelessly transferred to the tablet display where they are used to generate tactile images and provide information on a lesion's size, shape and hardness. The final report includes a tactile image of each lesion along with its user inputted location. The SureTouch System also includes a calibration and training phantom, a scale to ensure correct force applied during calibration procedures, and a holder for the wand.

Wireless Connection to Tablets / Phones

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181672

Device Name
SureTouch Mobile Pressure Mapping System

Indications for Use *(Describe)*
The SureTouch Mobile Pressure Mapping System is intended to p
documenting palpable breast lesions identified during a clinical b
Mapping System is intended for use by a qualified healthcare pro

Predicate Device: BreastView Visual Mapping System (DEN020001). This predicate device has not been subject to any design related recalls.

Device Description:

The SureTouch Mobile Pressure Mapping System ("SureTouch") is a computer-based device that produces a pressure map, called a tactile image, of specific areas of the breast as an aid to document lesions detected during a clinical breast exam. SureTouch utilizes a rechargeable, battery-powered hand-held wand (sensor unit) that incorporates a 30 x 40 mm array of pressure sensing elements to collect tactile data as the device is moved across the breast. Data collected using the wand are wirelessly transferred to the tablet display where they are used to generate tactile images and provide information on a lesion's size, shape and hardness. The final report includes a tactile image of each lesion along with its user inputted location. The SureTouch System also includes a calibration and training phantom, a scale to ensure correct force applied during calibration procedures, and a holder for the wand.

Digital Health Examples – Mobile Apps

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162647

Device Name
NuVasive® NuvaLine™ Mobile App

Indications for Use *(Describe)*

The NuVasive® NuvaLine™ Mobile App is a medical d
professionals in capturing, measuring, and storing spinal
care. The device allows the healthcare professional to co
images by featuring measurement tools on their mobile d

D. Device Description

The *NuVasive NuvaLine Mobile App* is a medical device software used to measure spinal pelvic and cervical parameters from an image of patient's x-rays taken with the device's camera. These measured parameters provide a quantifiable way to assess a patient's spinal deformity and correction correlated to health related quality of life (HRQOL) scores.

E. Indications for Use

The *NuVasive NuvaLine Mobile App* is a medical device software mobile application intended to assist healthcare professionals in capturing, measuring, and storing spinal alignment assessment images at various time points in patient care. The device allows the healthcare professional to conveniently perform and review spinal alignment assessments of images by featuring measurement tools on their mobile device.

Digital Health Examples – Mobile Apps

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162647

Device Name
NuVasive® NuvaLine™ Mobile App

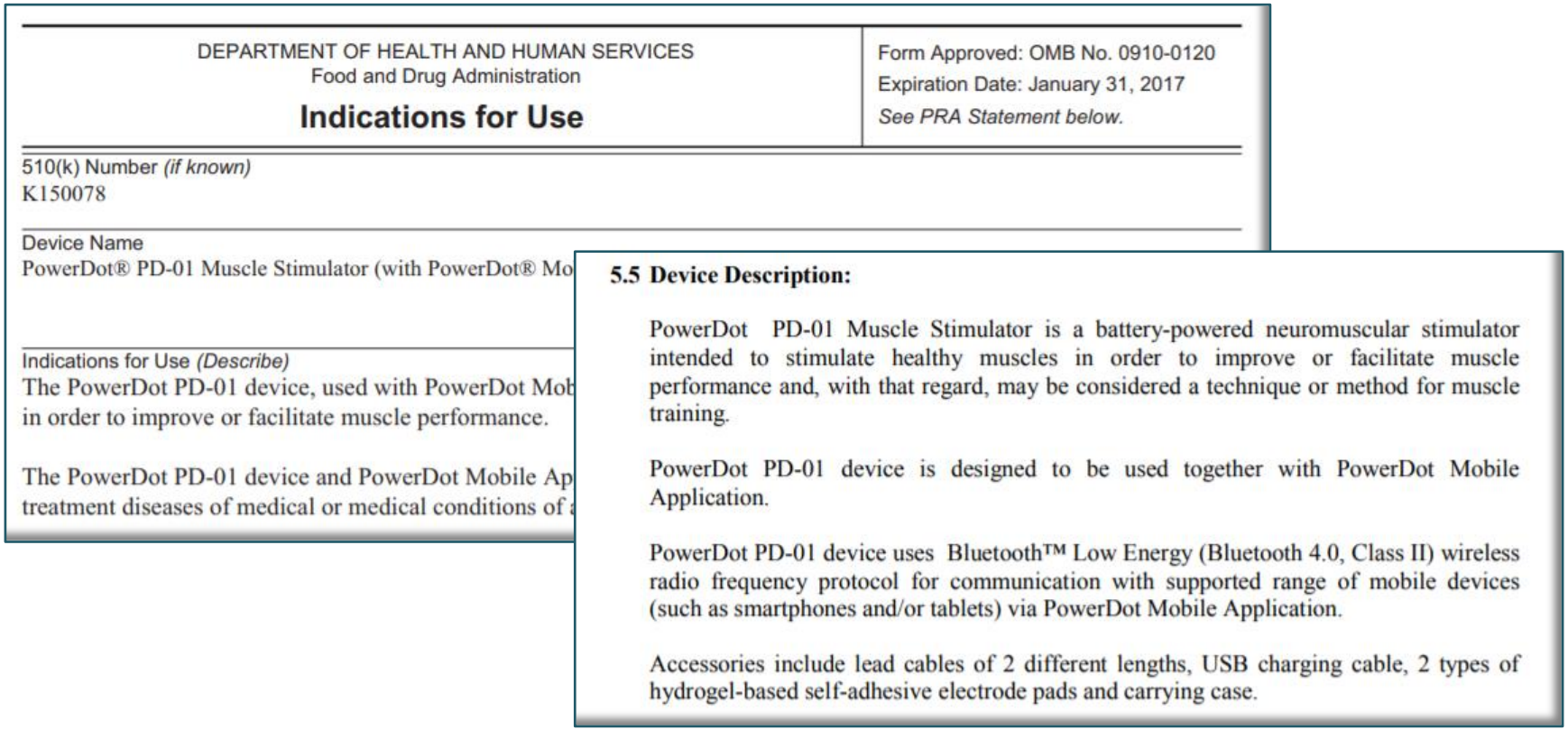
Indications for Use *(Describe)*
The NuVasive® NuvaLine™ Mobile App is a medical device software mobile application intended to assist healthcare professionals in capturing, measuring, and storing spinal alignment assessment images at various time points in patient care. The device allows the healthcare professional to conveniently perform and review spinal alignment assessments of images by featuring measurement tools on their mobile device.

K173232

lication Model APP1001 is as follows:

The myMerlin™ mobile application Model APP1001 is an application for patients who are implanted with the Confirm Rx™ Insertable Cardiac Monitor (ICM) Model DM3500 (K163407). The mobile application is used by patients to initiate recording of the heart's electrical activity by the Confirm Rx™ ICM device, read the information about the heart's activity from the Confirm Rx™ ICM device, and send this information to a clinician for remote monitoring. The myMerlin™ mobile application Model APP1001 is to be installed on a patient's mobile device with the iOS operating system which meets the specified minimum criteria for compatibility with the myMerlin™ mobile application.

Digital Health Examples – Post Cures Act



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150078

Device Name
PowerDot® PD-01 Muscle Stimulator (with PowerDot® Mo

Indications for Use *(Describe)*
The PowerDot PD-01 device, used with PowerDot Mob
in order to improve or facilitate muscle performance.

The PowerDot PD-01 device and PowerDot Mobile Ap
treatment diseases of medical or medical conditions of

5.5 Device Description:

PowerDot PD-01 Muscle Stimulator is a battery-powered neuromuscular stimulator intended to stimulate healthy muscles in order to improve or facilitate muscle performance and, with that regard, may be considered a technique or method for muscle training.

PowerDot PD-01 device is designed to be used together with PowerDot Mobile Application.

PowerDot PD-01 device uses Bluetooth™ Low Energy (Bluetooth 4.0, Class II) wireless radio frequency protocol for communication with supported range of mobile devices (such as smartphones and/or tablets) via PowerDot Mobile Application.

Accessories include lead cables of 2 different lengths, USB charging cable, 2 types of hydrogel-based self-adhesive electrode pads and carrying case.