# What is a *Regulated* Medical Device:

## *When do we need FDA's permission to market our device and when do we not?*


Presented by:

***Michael Drues, Ph.D.***

President, Vascular Sciences
Carlsbad, California

and

Adjunct Professor of Regulatory Science, Medicine and Biomedical Engineering

George Washington University Graduate Dept. of Regulatory Science

Cornell University Graduate Dept. of Biomedical Engineering


GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device


For questions or more information, call
(508) 887 – 9486 or e-mail mdrues@vascularsci.com

# What is a Regulated Medical Device?

## *When do we need FDA's permission to market our device and when do we not?*

presented by: ***Michael Drues, Ph.D.***

Before you stop reading because you think this topic is a no-brainer, think again! If your device fits the CFR definition of a medical device, its regulated by FDA. If it does not fit the CFR definition of a medical device, it is not regulated by FDA. Pretty straightforward… end of discussion, right? Maybe not.

A growing number of companies are getting warning letters from FDA for marketing devices without getting FDA's "permission" first. Other companies are wasting a lot of time and money taking devices to FDA that do not need to! Most importantly, some companies are missing huge opportunities to have a device regulated by FDA even though they may not be required!

In this workshop, we will explore the seemly simple question: *what is a regulated medical device?* and how we can *interpret* the CFR definition of a device to our advantage. Using the case study approach, these questions and others will be presented in an interactive fashion including:

- What is and is not a regulated medical device?
- Does it matter if your device is a mechanical widget? liquid? software? something else?
- Can a video game be regulated by FDA? what about a potato chip bag or chewing gum?
- What if your device never comes in contact with a patient?
- What if there are non-medical device functions within a regulated medical device (i.e., a so-called *multiple function device*)?
- If your device is not a regulated medical device, are there advantages of taking it to FDA anyway?
- Can a medical device be regulated by FDA *and* not regulated by FDA *at the same time?*

This is just the tip of the iceberg! Bottom line: there are multiple interpretations of the CFR definition of a medical device and there are advantages and disadvantages to each interpretation. So unless you understand all of the possibilities — not just the common ones – and the advantages and disadvantages to each – how can you decide which is best for you?

What to know more? See:

Podcast: *What is a multiple function device?* (Sept, 2020, GreenLight here)

For a comprehensive list of columns, webinar, podcasts, etc., visit Global Medical Device Podcast (GreenLight.Guru) here, Mike on MedTech (Medical Product Outsourcing) here, Medical Design and Outsourcing here, Guerilla Regulatory Strategy (MED Device Online) here and Healthcare Packaging here, LinkedIn here.

# Speaker Biography


Michael Drues, Ph.D., is a regulatory strategy consultant specializing in designing novel regulatory strategies to bring new and innovative medical products to market and in developing effective communication strategies between companies and regulatory agencies to minimize time to market and avoid delays.

Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University. He works with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. He also works on a regular basis for the U.S. Food and Drug Administration, Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services and other regulatory and governmental agencies around the world.

Dr. Drues is an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and regulatory affairs. He conducts seminars and short-courses for medical device, pharmaceutical and biotechnology companies, the FDA, Health Canada, the US and European Patent Offices, CMS and other regulatory and governmental agencies around the world.

Finally, Dr. Drues is an Adjunct Professor of Regulatory Affairs, Medicine and Biomedical Engineering at several universities and medical schools. He regularly teaches graduate courses in Medical Device Regulatory Affairs and Product Development, Combination Products, Regulatory Affairs and Clinical Trials, Clinical Trial Design and Pathophysiology.

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*


1


2

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## First, an important disclaimer...


**I can't make you an expert in a few minutes!**

I'm not even going to try but…

Remember my philosophy of education:

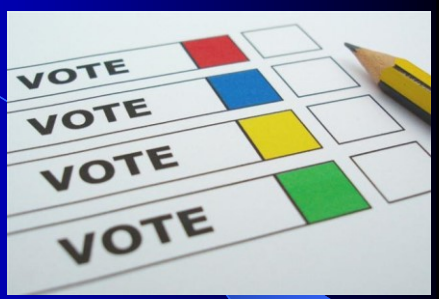
***To teach you how to think not what to think!***




3

*Before we begin…*

## Polling Question




Are you working on an FDA regulated medical device?

Are you working on a *non*-FDA regulated medical device?

Does your device have functions or components of both?

Do you think know the difference? ☺



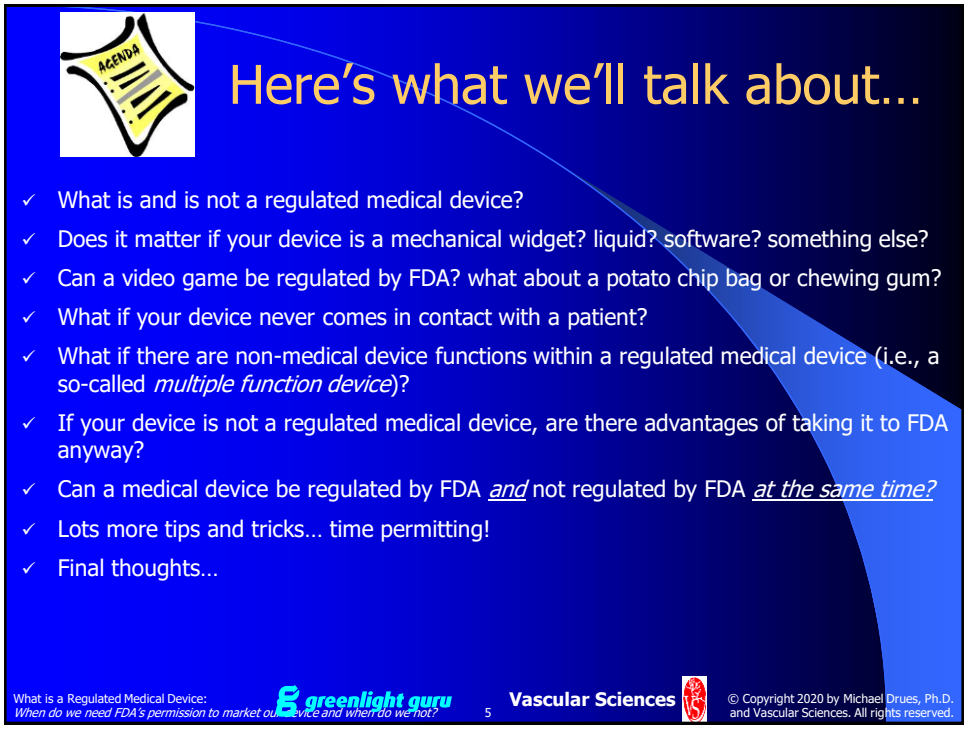

4

GreenLight.Guru Webinar (November 24, 2020)

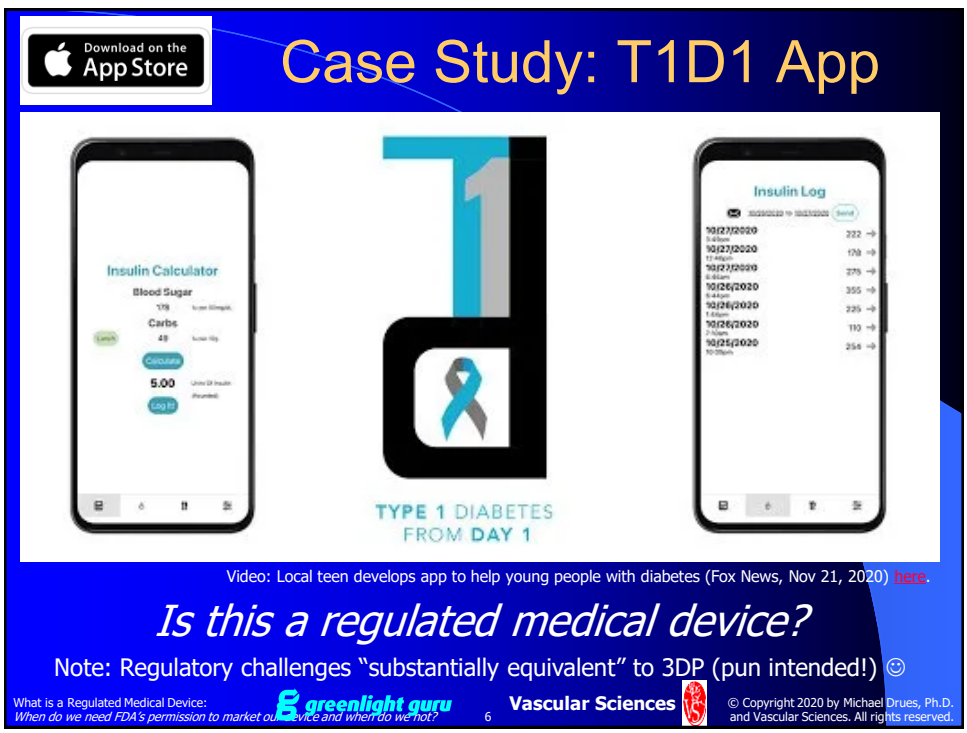
www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*




5




6

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## Can a video game be a regulated medical device

*The answer may not be what you think!*




7

## Case Study: EndeavorRx Video Game for ADHD


INSIGHT™ ADHD
our behavior tracking app

EndeavorRX Trailer (30 sec) here

EndeavorRx (DEN200026)
FDA Press release here
Product website here


"The first game-based therapeutic granted marketing authorization by the FDA for any type of condition. Available to patients without a prescription in April under FDA's enforcement discretion policy for digital health devices for treating psychiatric disorders during the coronavirus disease (COVID-19) public health emergency."

First video game-based treatment gets go ahead from FDA (RAPS, June, 2020) here.

*EUA → De novo*




8

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## What is a medical device

Short answer: *wrong question… to simple!*

Better question:

What is a FDA *non-regulated* medical device?

*vs.*

What is a FDA *regulated* medical device?

Must they be the same? Must they be different?




9

## Case Study: *Chip bag to prevent drunk driving*

Is this a medical device?

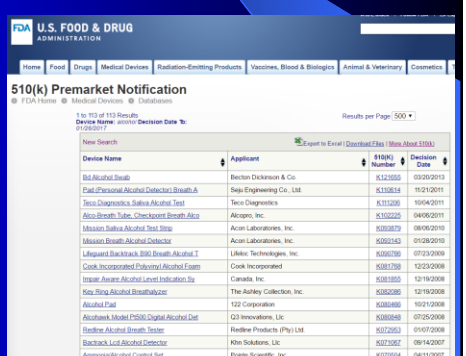

Video: *Chip bag to prevent drunk driving (Jan, 2017) (1 min)*
Another video here.

Before answering…

>100 'cleared' devices for alcohol detection including breath tests!

Is this chip bag any different?


510k list on cleared alcohol detection devices here (Jan, 2017)







10

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## Can chewing gum be a medical device?

Chewing gum can be food… can be drug or even combination product…

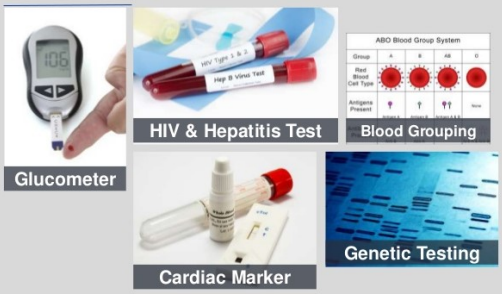
i.e., nicotine replacement therapy (NRT): nicotine gum, transdermal nicotine patch & nicotine lozenge

***Can gum be a medical device?***

## Case Study: *Cancer Detecting Chewing Gum*

## ***Boring! Let's get creative!***

### IN VITRO DIAGNOSTIC EXAMPLES




Why a medical device?
What kind of device?
What is the precedent?
and now…

Video: Cancer detecting chewing gum (ABC News, April 11, 2017) (2 min)




11

## How do we view the world?

***Discovery is seeing what everyone else has seen and thinking what no one else has thought.***

– Albert Szent-Gyorgi, 1937 Nobel Prize in Physiology and Medicine

Or put another way…

***It's not what you look at that matters, it's what you see.***

– Henry David Thoreau (1817–1862), American author, poet and philosopher

***So what do you see?***




12

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## What is a *non*-FDA regulated medical device

Short answer:

Something that *does not* fit the CFR definition of a medical device

What do we call it?

*Wellness Device* (consumer product)




13

## What is a general wellness product

Mike's Definition:

A device with 1) "weak" medical claims, 2) "well established" technology and 3) "*very low*" risk

Regarding claims…

*You can't make "direct" medical claims…*

*but you can infer/imply them!*

Note: Nothing new here… this has always been the case!



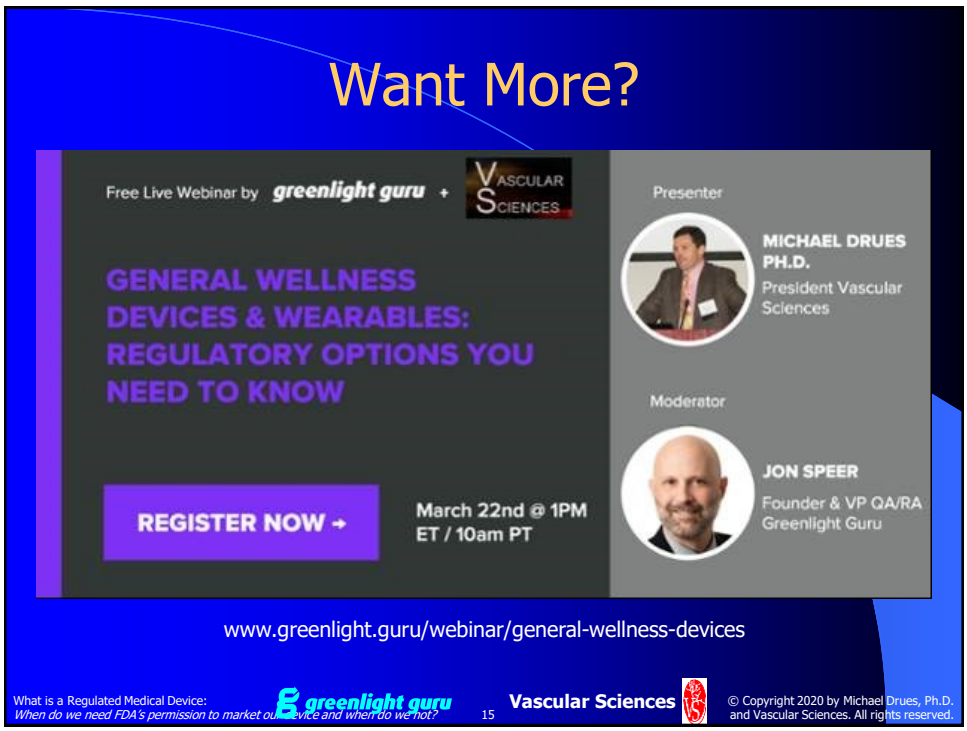

14

GreenLight.Guru Webinar (November 24, 2020)

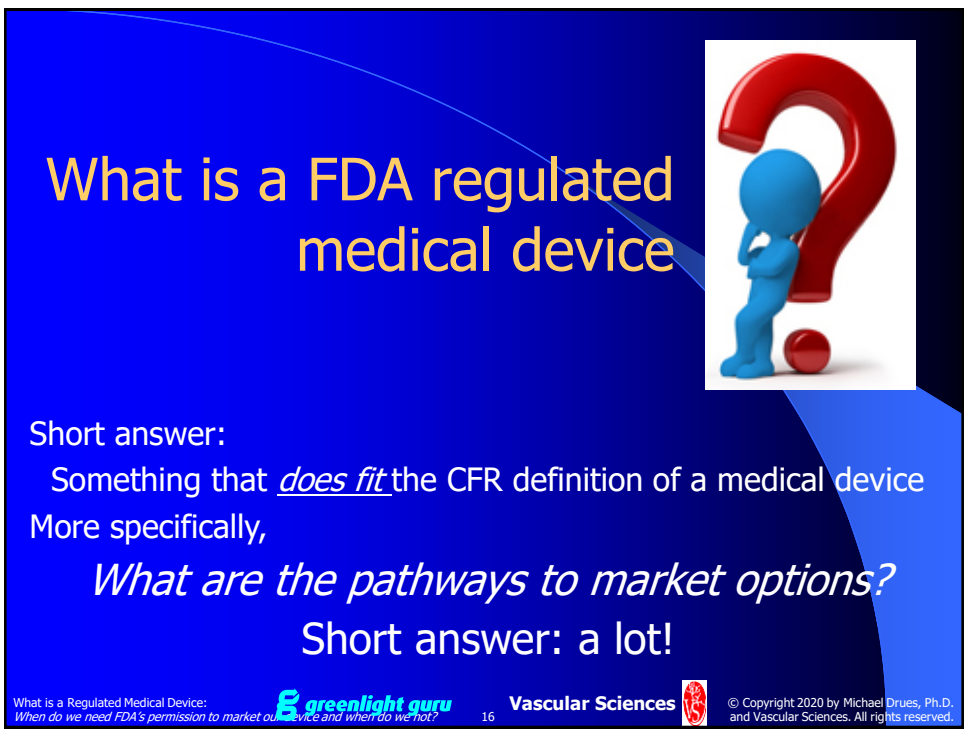
www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*




15



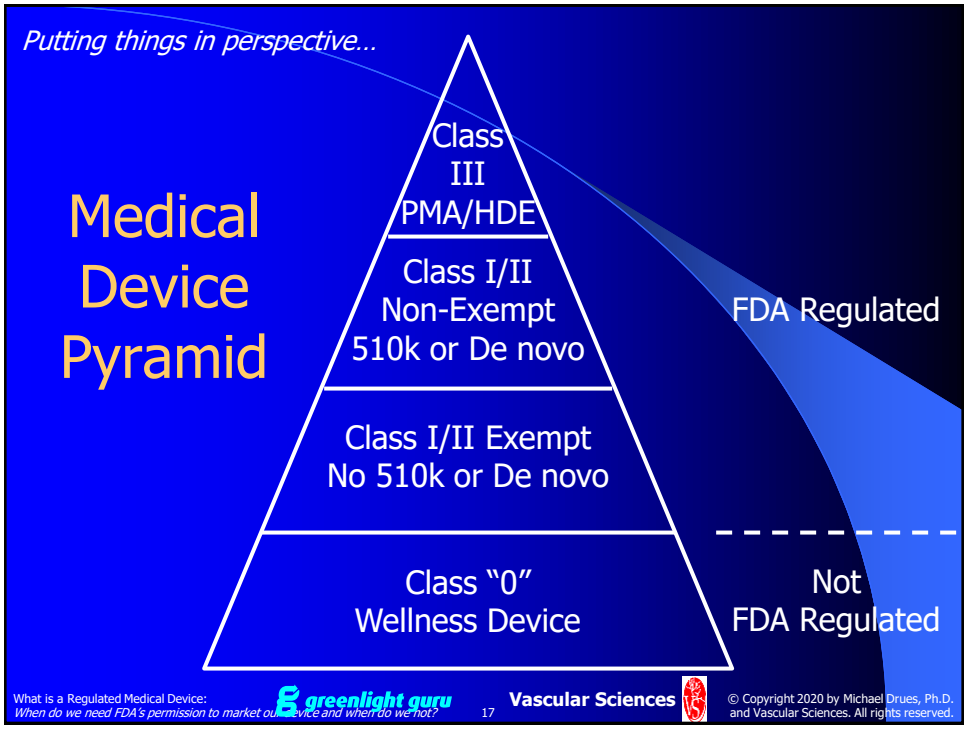

16

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*




17


18

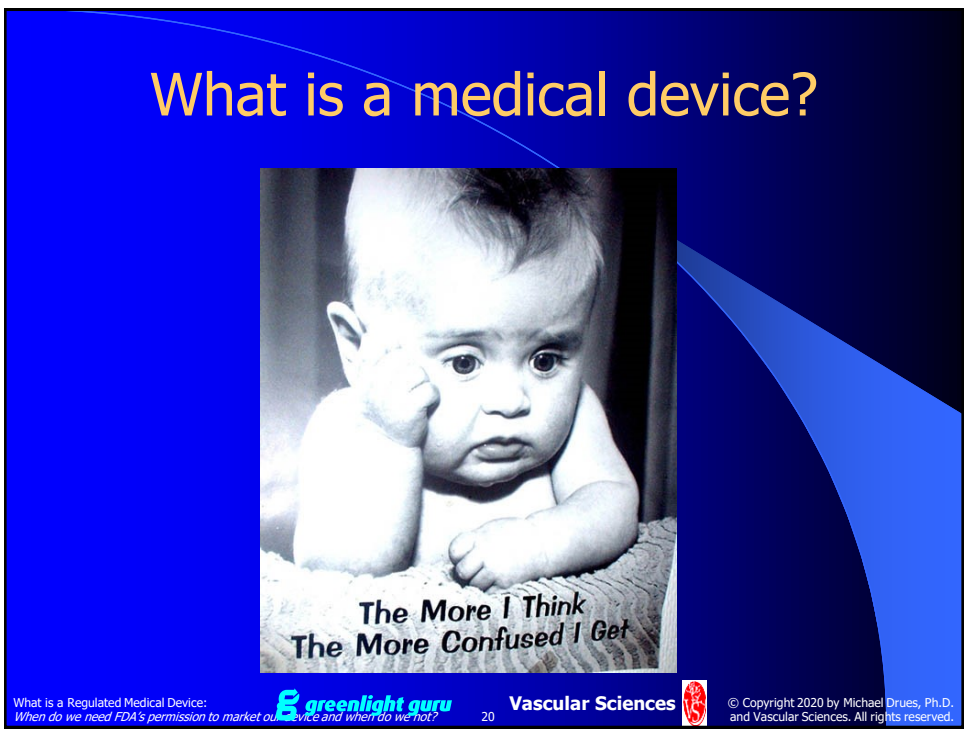
GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*


19




20

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

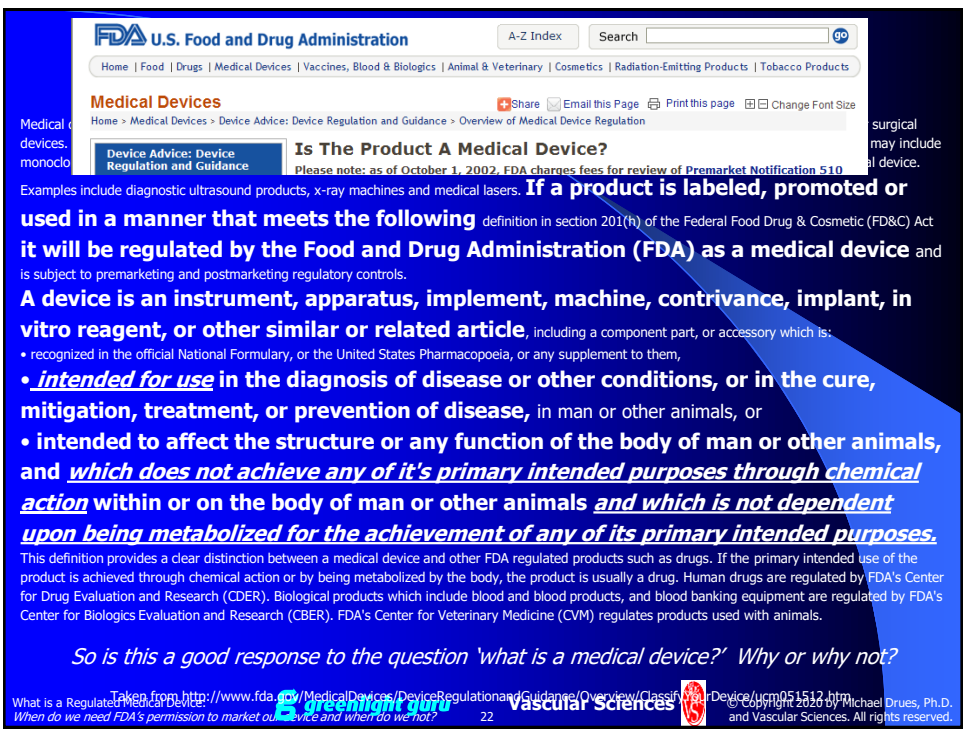
*When do we need FDA's permission to market our device and when do we not?*

## How about some regulatory





21




Examples include diagnostic ultrasound products, x-ray machines and medical lasers. **If a product is labeled, promoted or used in a manner that meets the following** definition in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act **it will be regulated by the Food and Drug Administration (FDA) as a medical device** and is subject to premarketing and postmarketing regulatory controls.

**A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article**, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- ***intended for use*** **in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease,** in man or other animals, or
- **intended to affect the structure or any function of the body of man or other animals, and *which does not achieve any of it's primary intended purposes through chemical action* within or on the body of man or other animals *and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.***

This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug. Human drugs are regulated by FDA's Center for Drug Evaluation and Research (CDER). Biological products which include blood and blood products, and blood banking equipment are regulated by FDA's Center for Biologics Evaluation and Research (CBER). FDA's Center for Veterinary Medicine (CVM) regulates products used with animals.

*So is this a good response to the question 'what is a medical device?' Why or why not?*

Taken from http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm




22

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## What's the *essence* of the CFR definition of a medical device

Something… anything, other than a drug, intended to (meaning you say) prevent, diagnose or treat a disease, injury or condition.

Bottom line:

If you *meet* this definition, you *are* a regulated medical device…

If you *don't meet* this definition, you *are not* a regulated medical device.

***It's that simple… or is it?***




23

## What is the true essence of regulation?

***Regulation is all about the interpretation of words…***

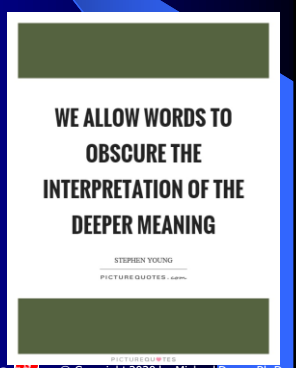
***and your ability to defend your interpretation!***

and why assume FDA's interpretation is the only one or the best one???

Happens in regulatory and quality all the time!

Most important…

***Understand the spirit of the law not just the letter of the law***







24

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## What is the international view?

Global Harmonization Task Force definition of a medical device:

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- investigation, replacement, modification, or support of the anatomy or of a physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices
- providing information by means of in vitro examination of specimens derived from the human body

and **does not achieve its primary intended action by pharmacological, immunological or metabolic means**, in or on the human body, but which may be assisted in its intended function by such means.

Note: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances,
- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,
- devices for *in vitro* fertilization or assisted reproduction technologies.

GHTF, May, 2012

*Is the above not 'substantially equivalent' to the CFR?*

Note: pun intended! ☺




25

## Definition of Medical Device

1. Primary mode of action (PMOA) is mechanical or electrical


Source: US FDA CDRH 2005 Strategic Plan

2. Broad range of examples from wheel chairs and EKG monitors thru the totally implantable artificial heart!




26

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## Definition of Medical Device

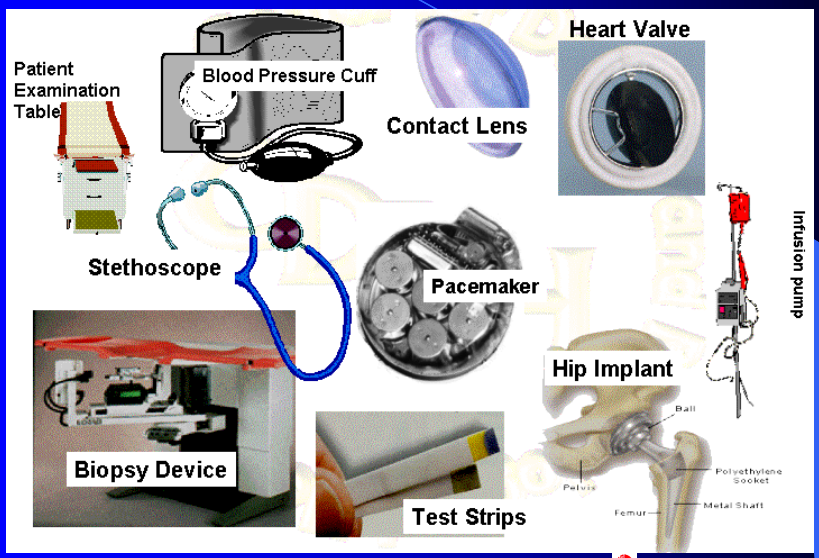
1. Primary mode of action (PMOA) is mechanical or electrical


2. Broad range of examples from wheel chairs and EKG monitors thru the totally implantable artificial heart!




27

## Examples of Medical Devices...







28

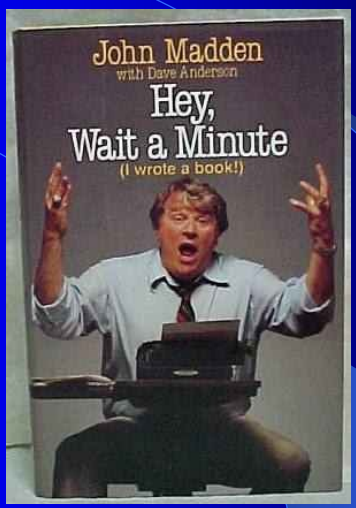
GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## Hey, wait a minute…




*Maybe life isn't quite so simple!*




29

## What if your device has functions of regulated medical devices *and* functions of non-regulated devices in one package

"Multiple Function Device Products" *– not a great name!*

*The lines are getting blurry and many more of these in the future!*




30

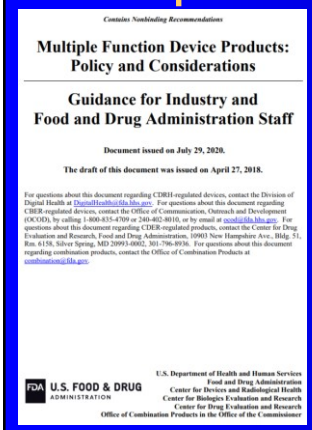
GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## Multiple Function Device Products



Contains Nonbinding Recommendations

**Multiple Function Device Products: Policy and Considerations**

**Guidance for Industry and Food and Drug Administration Staff**

**Document issued on July 29, 2020.**

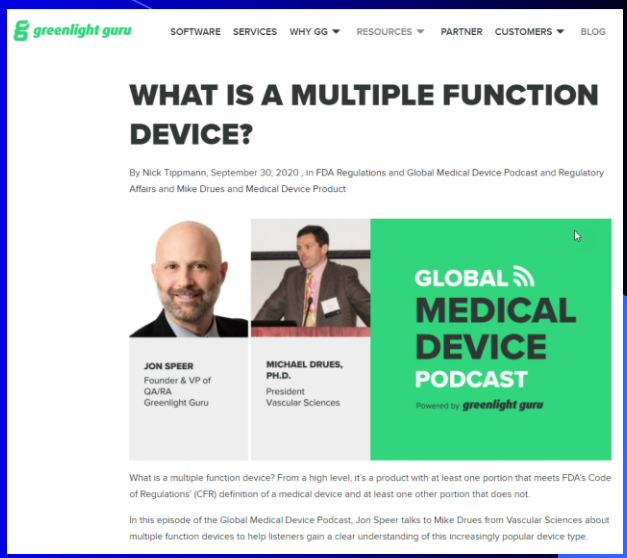
**The draft of this document was issued on April 27, 2018.**

For questions about this document regarding CDRH-regulated devices, contact the Division of Digital Health at DigitalHealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact the Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6158, Silver Spring, MD 20993-0002, 301-796-8936. For questions about this document regarding combination products, contact the Office of Combination Products at combination@fda.gov.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Office of Combination Products in the Office of the Commissioner

CDRH Guidance (July, 2020) here.



greenlight guru SOFTWARE SERVICES WHY GG RESOURCES PARTNER CUSTOMERS BLOG

**WHAT IS A MULTIPLE FUNCTION DEVICE?**

By Nick Tippmann, September 30, 2020 , In FDA Regulations and Global Medical Device Podcast and Regulatory Affairs and Mike Drues and Medical Device Product

JON SPEER
Founder & VP of QA/RA
Greenlight Guru

MICHAEL DRUES, PH.D.
President
Vascular Sciences

GLOBAL MEDICAL DEVICE PODCAST
Powered by greenlight guru

What is a multiple function device? From a high level, it's a product with at least one portion that meets FDA's Code of Regulations' (CFR) definition of a medical device and at least one other portion that does not.

In this episode of the Global Medical Device Podcast, Jon Speer talks to Mike Drues from Vascular Sciences about multiple function devices to help listeners gain a clear understanding of this increasingly popular device type.

Podcast (Sept, 2020) here.




31

## Multiple Function Device Products

WHAT IS A MULTIPLE FUNCTION DEVICE?

GLOBAL MEDICAL DEVICE PODCAST

Podcast (Sept, 2020) here.

Key takeaways:

- ✓ A multiple function device is a product that has *at least one function that meets CFR's definition of a medical device, and one non-device function that does not* meet CFR's definition of a medical device.
- ✓ A *combination product is not a multiple function device.* However, the device portion of the combination product could offer multiple functions that meet CFR's medical device definition.
- ✓ *Examples* of multiple function devices include *smartphones with camera apps to detect skin cancer*, while other functions could but should not impact the safety, effectiveness, and performance of the regulated version of the product.
- ✓ FDA Assessment: *Direct or indirect regulatory review* of multiple function devices is confusing and complex. It's not an excuse for not prudent engineering.
- ✓ FDA Flowchart: *Is there an impact on the safety or effectiveness of the device function under review as a result of the other function?*
- ✓ Regulatory Strategy Recommendation: *Decouple technologies and functions to consider each separately, then recombine and rebuild as a system.*




32

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## How can you determine if your device is FDA regulated or not

Short answer: *its not always straight forward!*

Two Options:

1. 513g
2. Device determination mailbox




33

## Request for Information

- Also known as the 513(g) but remember…
  *This is a process not a form!*
- FDA has 60 days to respond (in theory)
- Note: User fees apply!

"Typical" 513(g) inquiries to date:

- Is device subject to FDA regulation?
- Is device exempt from 510(k) requirements (Class 0?)
- Does modification of existing marketed device require new 510(k)? [i.e., 'special' 510(k)]
- If new device introduces new technology/new intended use, what is regulatory pathway?

See CDRH on-line presentation here for more.

What about a

*Request for RE-Classification?*

*FDA does it (occasionally)… you can to!*

CDRH Guidance: 513(g) Requests for Information (2019) here

*Contains Nonbinding Recommendations*

**FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act**

**Guidance for Industry and Food and Drug Administration Staff**

**Document issued on December 16, 2019.**

**Document originally issued on December 21, 2015.**

**This document supersedes, FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act, issued December 21, 2015.**

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0705 (expires 6-30-2021).

**See additional PRA statement in Section IX of the guidance.**

For questions for the Center for Devices and Radiological Health regarding this document, contact ORP: Office of Regulatory Programs/Division of Regulatory Programs 1: Submission Support at 301-796-5640. For questions for the Center for Biologics Evaluation and Research regarding this document contact the Office of Communication, Outreach and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Centers for Biologics Evaluation and Research




34

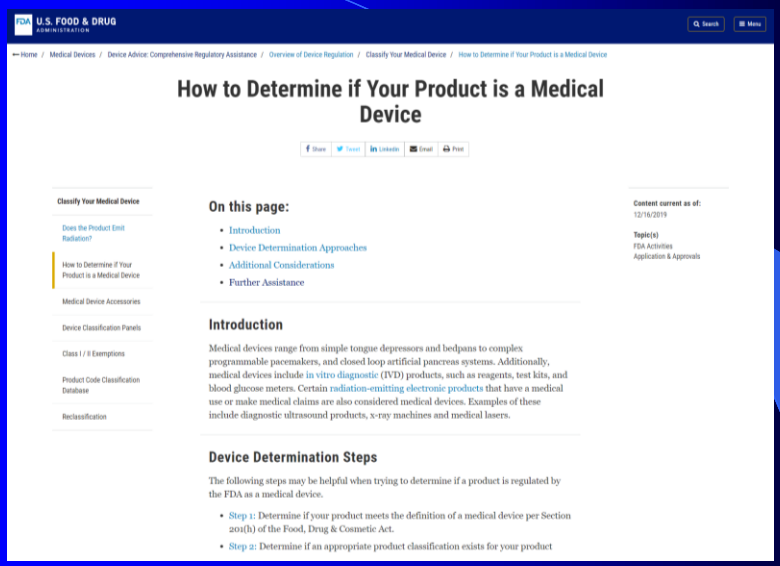
GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## What does FDA Recommend?



U.S. FOOD & DRUG ADMINISTRATION

Home / Medical Devices / Device Advice: Comprehensive Regulatory Assistance / Overview of Device Regulation / Classify Your Medical Device / How to Determine if Your Product is a Medical Device

**How to Determine if Your Product is a Medical Device**

Classify Your Medical Device
- Does the Product Emit Radiation?
- How to Determine if Your Product is a Medical Device
- Medical Device Accessories
- Device Classification Panels
- Class I / II Exemptions
- Product Code Classification Database
- Reclassification

**On this page:**
- Introduction
- Device Determination Approaches
- Additional Considerations
- Further Assistance

Content current as of: 12/16/2019

Topic(s): FDA Activities, Application & Approvals

**Introduction**

Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers, and closed loop artificial pancreas systems. Additionally, medical devices include in vitro diagnostic (IVD) products, such as reagents, test kits, and blood glucose meters. Certain radiation-emitting electronic products that have a medical use or make medical claims are also considered medical devices. Examples of these include diagnostic ultrasound products, x-ray machines and medical lasers.

**Device Determination Steps**

The following steps may be helpful when trying to determine if a product is regulated by the FDA as a medical device.

- Step 1: Determine if your product meets the definition of a medical device per Section 201(h) of the Food, Drug & Cosmetic Act.
- Step 2: Determine if an appropriate product classification exists for your product

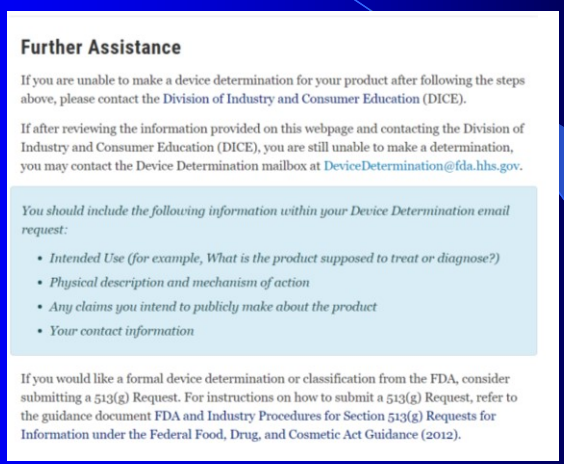
From here

*Does this answer your question?*




35

## Another option:
## Device Determination "Pathway"



**Further Assistance**

If you are unable to make a device determination for your product after following the steps above, please contact the Division of Industry and Consumer Education (DICE).

If after reviewing the information provided on this webpage and contacting the Division of Industry and Consumer Education (DICE), you are still unable to make a determination, you may contact the Device Determination mailbox at DeviceDetermination@fda.hhs.gov.

*You should include the following information within your Device Determination email request:*
- *Intended Use (for example, What is the product supposed to treat or diagnose?)*
- *Physical description and mechanism of action*
- *Any claims you intend to publicly make about the product*
- *Your contact information*

If you would like a formal device determination or classification from the FDA, consider submitting a 513(g) Request. For instructions on how to submit a 513(g) Request, refer to the guidance document FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act Guidance (2012).

From here

*Simple, quick, free… but non-binding.*




36

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## Is this a medical device?

Short answer: *it depends!*

What's the intended use?

If we use it this way…

it's a medical device

But if we use it this way…

it's not!

Same shape?
Same size?
Same materials?
Same part of the body?
i.e., don't both go inside the mouth?

*So is this a distinction without a real difference?*




37

## Case Study:
## *Intended Use vs. Indications for Use*

Are they the same?

*i.e., are the substantially equivalent, are they bioequivalent?*




38

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## Intended Use vs. Indications for Use

- Many use synonymously but not the same – although there often overlap
- Both 'high-level' labeling

Indications for Use:

- Focus on ***patient***, i.e., what diseases, injuries, conditions, etc. does product diagnose, treat, etc.
- *Indications* for Use (IFU) ≠ *Instructions* for Use (IFU) = Directions for Use (DFU)

Intended Use:

- Focus on ***product***, i.e., what does device/drug actually do (i.e., how does it work?)

Labeling Recommendations

- Start broadly – can narrow if necessary – be prepared to negotiate
- Stated vs. inferred/implied label claims
- Design high-level labeling just like design product
- Take advantage of label expansions
- Think outside the regulatory box – reimbursement, product liability, etc.
- Consider contraindications only as last resort

*This is not rocket science – but it is a poker game – strategy is key!*




39

## Is this a medical device?

No? Perhaps not but… *could it be?*

Hint: look at the label

Note: Similar to a nutraceutical claims.

Remember,

***It's not simply <u>what</u> you say that matters…***

***it's <u>how</u> you say it!***

So…

We don't need to change the product to create a medical device… simply what we say!





40

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## Case Study: Mirrors

Is a mirror a regulated medical device?
It depends… what kind of mirror?

Five FDA product codes for mirrors:

FDA U.S. FOOD & DRUG ADMINISTRATION

SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Product

**Product Classification**

FDA Home > Medical Devices > Databases

1 to 5 of 5 results
*mirror*

Results per page 500

New Search | Export to Excel | Help

| Product Code | Device | | Regulation Number | Device Class |
|---|---|---|---|---|
| GCO | Endoscope, Mirror | Endoscope And Accessories | 876.1500 | 2 |
| KAI | Mirror, Ent | Ear, Nose, And Throat Manual Surgical In... | 874.4420 | 1 |
| FTX | Mirror, General & Plastic Surgery | Manual Surgical Instrument For General U... | 878.4800 | 1 |
| HKF | Mirror, Headband, Ophthalmic | Headband Mirror | 886.1500 | 1 |
| EAX | Mirror, Mouth | Dental Hand Instrument | 872.4565 | 1 |




41

## Is a computer keyboard a medical device?

Wait, not so fast…

What if it's self-sanitizing?

What if it's used in hospitals?

Therefore,

***A computer keyboard can be a regulated medical device!***

The FDA has **cleared** the Vioguard self-sanitizing computer keyboard for use in hospitals and clinics.

Computers are becoming more common in hospitals because of electronic medical records, and shared keyboards are one of the major ways that disease can spread. The Ultraviolet "Class C" light used by the Vioguard keyboard is a well-known germicide. Vioguard cites outside lab tests showing the effectiveness of its system, which **it claims can rid highly contaminated keyboards of bacteria related to the deadly MRSA infection and other diseases in as little as 10 seconds.** Vioguard was awarded a patent in December, and ***the keyboard went through a clinical trial.*** The results were recently published in the American Journal of Infection.

"We're very pleased with the FDA clearance, which substantiates our medical claims and allows hospitals and clinics to make use of this new tool," Larry Ranta, president and CEO of Vioguard, said in a statement Tuesday. "Conventional computer keyboards have been identified as a key point of transmission of viruses and bacteria, especially within the medical setting. The Vioguard keyboard takes the guesswork out of sanitization efforts, reduces labor costs, and helps fight the spread of harmful and often deadly superbugs." DEN100013 (2011)

Puget Sound Business Journal, Jan. 3, 2012




42

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## Case Study: Copper Fit Energy Socks

Is this a regulated medical device?

Why or why not?

CFR Definition of Medical Device here

If not a regulated device, *could it be?*

Hint: *what would we have to change?*

If a regulated device, what are the options?

Wellness → Class I Exempt → Class II (510k or de novo) → higher?

*Copper Fit Energy Socks* video available here.





43

## Its all about what you say!

Pathway options:

Wellness

↓

Class I Exempt

↓

Class II

(510k or de novo)

↓

higher?

CFR 880.5780 here

Product Codes here

**Why do I have to choose…**

**Can you say label expansion?**

TITLE 21--FOOD AND DRUGS
SUBCHAPTER H--MEDICAL DEVICES

Subpart F--General Hospital and Personal Use Therapeutic Devices

(a) *Medical support stocking to prevent the pooling of blood in the legs --(1) Identification.* A medical support stocking to prevent the pooling of blood in the legs is a device that is constructed of elastic material and designed to apply controlled pressure to the leg and that is intended for use in the prevention of pooling of blood in the leg.

(2) *Classification.* Class II (performance standards).

**or**

(b) *Medical support stocking for general medical purposes --(1) Identification.* A medical support stocking for general medical purposes is a device that is constructed of elastic material and designed to apply controlled pressure to the leg and that is intended for medical purposes other than the prevention of pooling of blood in the leg.

(2) *Classification.* Class I. 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. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

**Product Classification**

FDA Home ⊙ Medical Devices ⊙ Databases

1 to 3 of 3 Results
880.5780

Results per Page 5

New Search Export to Excel Help

| Product Code | Device | | Regulation Number | Device Class |
|---|---|---|---|---|
| LLK | Legging, Compression, Non-Inflatable | Medical Support Stocking | 880.5780 | 2 |
| FQL | Stocking, Medical Support (For General Medical Pur ... | Medical Support Stocking | 880.5780 | 1 |
| DWL | Stocking, Medical Support (To Prevent Pooling Of B ... | Medical Support Stocking | 880.5780 | 2 |



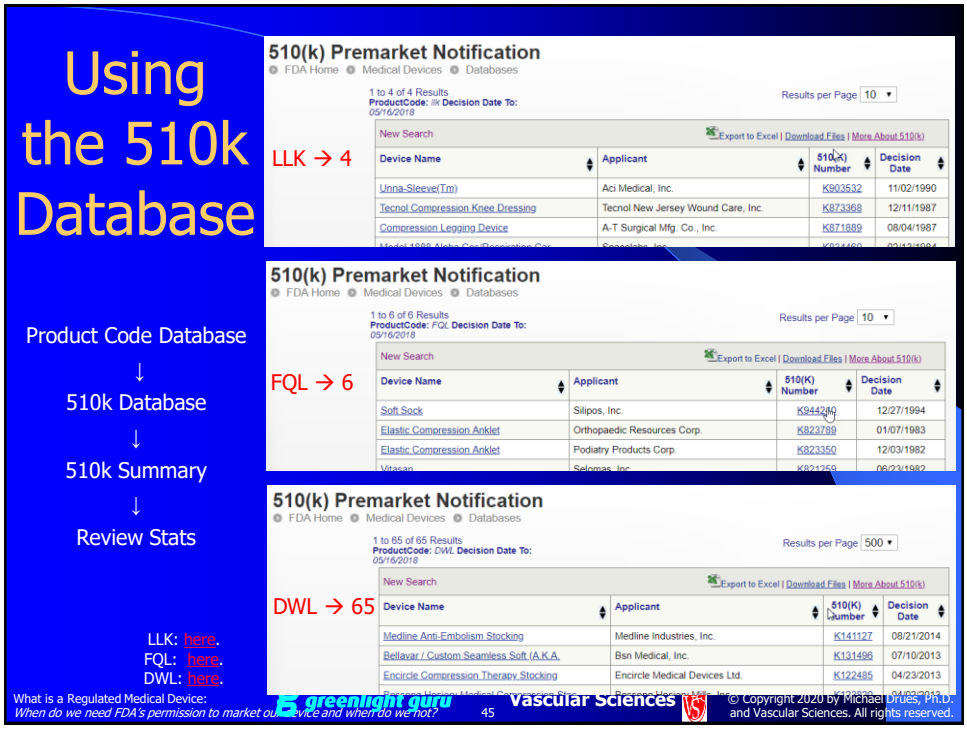

44

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*




45


46

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## Bringing Devices to Market: *Three Step Process*

1. Not PMA, 510k, de Novo, HDE or CDE but…

   ***Is it a regulated medical device?***

2. What classification?
   - Class I, Class II, Class III
   - Depends on level of "risk"
3. Select appropriate marketing application, i.e., regulatory pathway




47

## Is a *heated back wrap* a medical device?

**Heat therapy proves better than pain medication (ibuprofen & acetaminophen) for relieving back pain.**

Sports medicine researchers at the University of Medicine and Dentistry of New Jersey (UMDNJ) have concluded that **heat wrap therapy** is more effective for relieving lower back pain than drugs such as **ibuprofen** and **acetaminophen**.

The results were published in Spine Magazine. In the six-month study involving 371 patients, participants were given the maximum recommended non-prescription dosages of ibuprofen and acetaminophen or heat wrap therapy for two days to treat acute lower back pain.

The results showed that the heat wrap therapy provided significantly more pain relief beginning on the first day of treatment than the oral pain relief medications, and that the effects lasted more than 48 hours after the treatment was completed.

Dr. Nadler states, "Confirming that this [heat therapy] treatment is effective is important to patients because it gives them a treatment option that does not have the potential risk to the liver, kidneys, and gastrointestinal tract than can accompany inappropriate analgesic (oral pain medication) usage." The heat wrap treatments for low back pain also proved to be "better than oral analgesics because it goes beyond pain relief to provide muscle relaxation and increased flexibility."

Low back pain is the leading cause of disability in people under age 45 and the cost to society is estimated to range from $20 to $50 billion per year, according to statistics provided by the Agency for Healthcare Policy and Research of the U.S. Department of Health and Human Services.

A Warm Buddy **Sports Therapy Wrap** (pictured below) or **Body Wrap** is the perfect heat wrap to help relieve lower back pain. Warm Buddy products promote relaxation and provide natural relief from aches, pains and stress.

A Warm Buddy Heat Wrap has all natural ingredients that promote relief from aches, pain and stress. Clinical studies have shown heat wrap therapy to comfort back pain better than medications such as ibuprofen and acetaminophen.

http://www.warmbuddy.com/

Warm Buddy Receives Green Light from Health Canada (October 24, 2011)

After more than a year of dealing with regulatory hoops, the Warm Buddy Company has announced that its products have now been classified by Health Canada as an ***official medical device.***

**[Why bother?]**

"We are thrilled that as a result of our new medical device designation, we are not only back in business full steam, [because] ***now [we] have the ability to make medical claims for our products,"*** says McKee, a former registered nurse who worked with chronic pain patients.




48

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

## What about a leech?

**Or maybe leeches should be considered combination products?**

***Why?***

**Hint: Primary action is mechanical**

**Secondary action is secretion of anticoagulant-like proteins**

**Sound familiar…**

**can you say Drug-Eluting Stent?**

*It's a medical device… not a biologic!*

*Why… what is the regulatory justification?*

*Hint: How is primary task accomplished… biological or mechanical?*




49

## How do we view the world?

"Discovery is seeing what everyone else has seen and thinking what no one else has thought."

Albert Szent-Gyorgi,
1937 Nobel Prize in Physiology and Medicine

Or put another way…

Average regulatory professionals see a leech and think a leech…

better regulatory professionals see a leech and think a syringe…

the best regulatory professionals see a leech and think a pre-loaded syringe!

*So what do you see?*




50

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*


51


52

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device

# What is a Regulated Medical Device:

*When do we need FDA's permission to market our device and when do we not?*

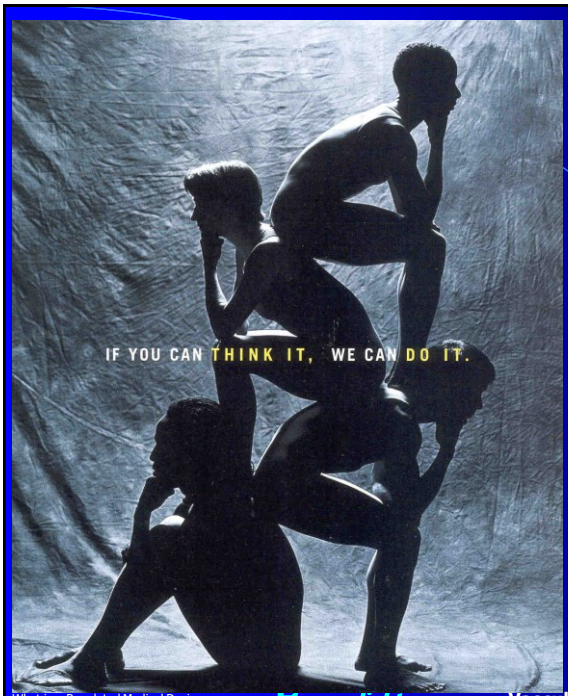
## Don't just follow the rules… think!

***Rules are mostly made to be broken***
***and are too often for the lazy to hide behind.***

General Douglas MacArthur (1880 –1964) was an American general in the US Army during the 1930s and played a prominent role in the Pacific theater during World War II. He was one of only five men ever to rise to the rank of General of the Army in the U.S.

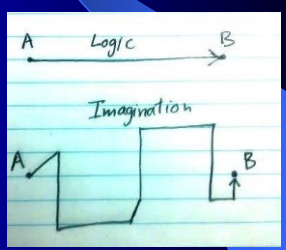



53




"Imagination is more important than knowledge, for while knowledge points to all there is, imagination points to all that can be."

Albert Einstein




"Logic will get you from A to B. Imagination will take you anywhere."

Albert Einstein




54

GreenLight.Guru Webinar (November 24, 2020)

www.greenlight.guru/webinar/when-do-we-need-fda-permission-to-market-device