

What is a Regulated Medical Device:

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

Presented by:

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and

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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 seemingly 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.

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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!

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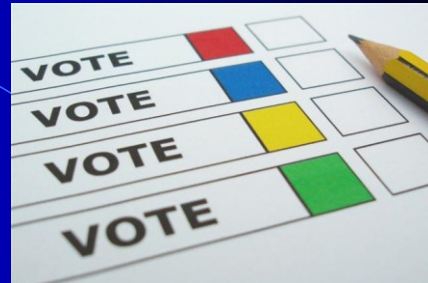


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Before we begin...

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? ☺

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




Here's what we'll talk about...

- ✓ 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?
- ✓ Lots more tips and tricks... time permitting!
- ✓ Final thoughts...




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Case Study: T1D1 App





TYPE 1 DIABETES FROM DAY 1

Video: Local teen develops app to help young people with diabetes (Fox News, Nov 21, 2020) [here](#).

Is this a regulated medical device?

Note: Regulatory challenges "substantially equivalent" to 3DP (pun intended!) ☺

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Can a video game be a regulated medical device



The answer may not be what you think!

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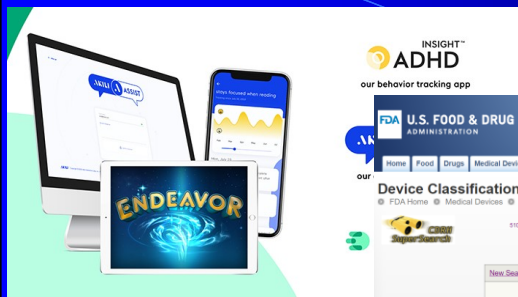
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Case Study: EndeavorRx Video Game for ADHD



EndeavorRx Trailer (30 sec) [here](#)

EndeavorRx ([DEN200026](#))
FDA Press release [here](#)
Product website [here](#)

INSIGHT™
ADHD
our behavior tracking app

U.S. FOOD & DRUG ADMINISTRATION	
Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products	
Device Classification Under Section 513(f)(2)(De Novo)	
FDA Home Medical Devices Databases	
510(k) De Novo Registration & Listing Adverse Events recalls PMA HDE Classification Standards	
CFR Title 21 Radiation-Emitting Products X-Ray Assembly Medical Reports GLA SPLC	
New Search	
De Novo Number	DEN200026
Device Name	EndeavorRx
Requester	ARI Interactive Labs Inc. 125 Broad Street, 4th Floor Boston, MA 02110 Scott Kellogg
Contact	
Classification Product Code	CPT
Date Received	04/16/2020
Decision Date	06/15/2020
Decision	Granted (DEN2)
Review Advisory Committee	Neurology
Reclassification Order	Reclassification Order
Type	Direct

"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

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What is a medical device



Short answer: *wrong question... too 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?

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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)

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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

Glucometer

HIV & Hepatitis Test

Blood Grouping

Cardiac Marker

Genetic Testing

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)

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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?

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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)

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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!

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Presenter



MICHAEL DRUES PH.D.
President Vascular Sciences

Moderator



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Founder & VP QA/RA
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www.greenlight.guru/webinar/general-wellness-devices

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What is a FDA regulated medical device



Short answer:
Something that does fit the CFR definition of a medical device
More specifically,
What are the pathways to market options?
Short answer: a lot!

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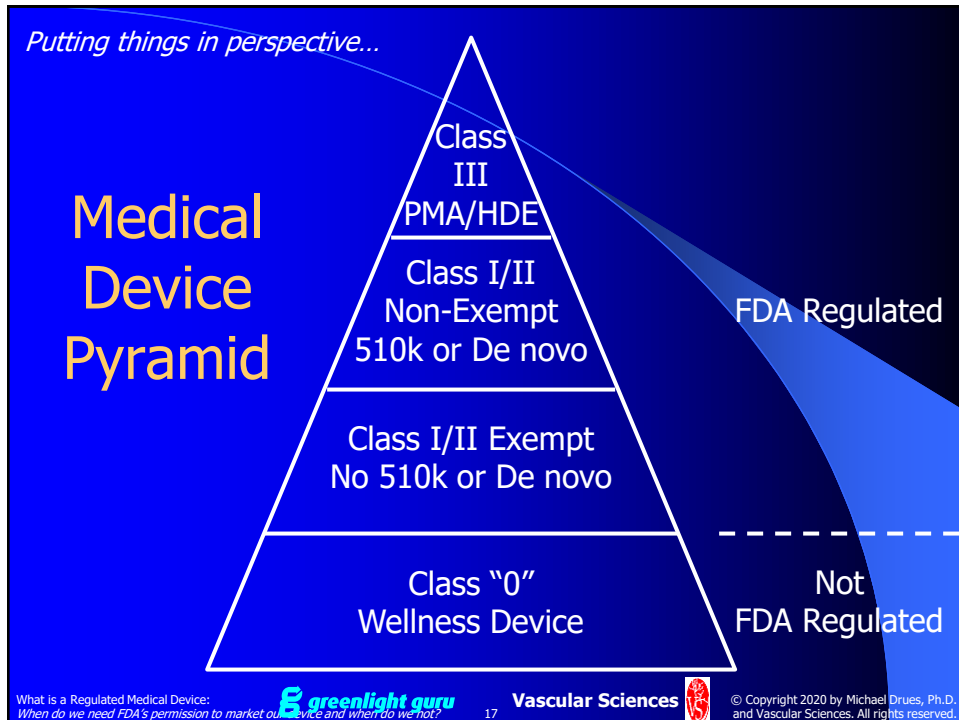
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How many ways (i.e., pathways) are there to get medical devices on to the market in the United States?

Not so short list:

1. Wellness Exemption
2. Class I Exempt / Class II Exempt
3. Pre-Market Notification a.k.a. 510k
4. De Novo
5. Pre-Market Approval (PMA)
6. Humanitarian Device Exemption (HDE)
7. Custom Device Exemption (CDE)
8. Expanded Access Pathway
9. Emergency Use Authorization (EAU)

Plus:

Breakthrough Devices Program (BDP) and Safer Technologies Program (STeP)

BDP and STeP are not pathways *per se* but certainly worth considering

...and you can even mix and match!
Combination products?
Combination Regulatory Strategy

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Pathways to Market Webinar

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April 2nd @
1:00p ET / 10:00a PT

Presenter

MICHAEL DRUES, PH.D.
President at Vascular Sciences

Moderator

JON SPEER
Founder & VP of QA/RA at Greenlight Guru


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What is a medical device?



**The More I Think
The More Confused I Get**

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How about some regulatory



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FDA U.S. Food and Drug Administration

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Medical Devices

Home > Medical Devices > Device Advice: Device Regulation and Guidance > Overview of Medical Device Regulation

Is The Product A Medical Device?

Please note: as of October 1, 2002, FDA charges fees for review of Premarket Notification 510

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/ClassifyingMedicalDevices/ucm051512.htm>

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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?

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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***



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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! ☺

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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!

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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!

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

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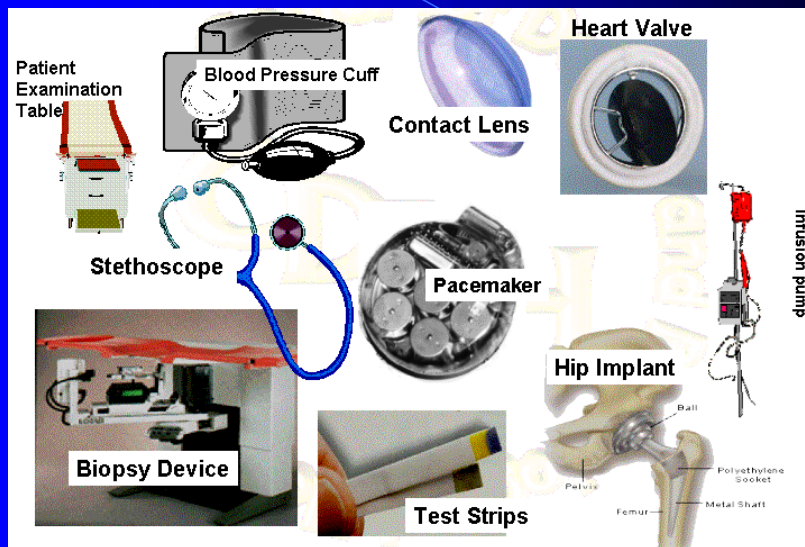
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Examples of Medical Devices...



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

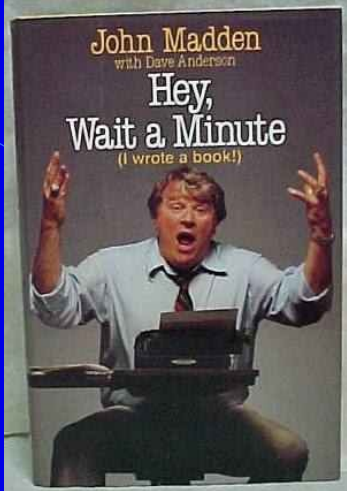
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What is a Regulated Medical Device:




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!

What is a Regulated Medical Device:
When do we need FDA's permission to market our device and when do we not?

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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!

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

Multiple Function Device Products

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 CDREH-regulated devices, contact the Division of Digital Health at DigitalHealth@fda.hhs.gov. For questions about this document regarding CDREH-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-635-6709 or 240-402-6010, or by email at ocod@fda.hhs.gov. For questions about this document regarding CDREH-regulated products, contact the Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., 5th Fl., Rm. 615B, Silver Spring, MD 20993-0002, 301-796-8076. For questions about this document regarding combination products, contact the Office of Combination Products at ocp@fda.hhs.gov.

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](#).

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 QARA
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.

What is a Regulated Medical Device: *When do we need FDA's permission to market our device and when do we not?*

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Multiple Function Device Products

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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.*

Podcast (Sept, 2020) [here](#).

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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

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

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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

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

What does FDA Recommend?

The screenshot shows the FDA's guidance page for determining if a product is a medical device. The page is titled 'How to Determine if Your Product is a Medical Device' and includes a sidebar with navigation links such as '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', and 'Reclassification'. The main content area includes an 'Introduction' section explaining that medical devices range from simple tongue depressors to complex programmable pacemakers, and a 'Device Determination Steps' section listing two steps: 1. Determine if your product meets the definition of a medical device per Section 201(h) of the Food, Drug & Cosmetic Act, and 2. Determine if an appropriate product classification exists for your product. The page also includes social media sharing options and a 'Contact current as of: 12/16/2019' note.

From [here](#)

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Another option: Device Determination "Pathway"

The screenshot shows the 'Further Assistance' section of the FDA's guidance page. It explains that if a user is unable to make a device determination after following the steps above, they should contact the Division of Industry and Consumer Education (DICE). It also provides the email address DeviceDetermination@fda.hhs.gov for contacting the Device Determination mailbox. A list of information to include in the request is provided: 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, and Your contact information. The page also mentions that if a formal device determination or classification is needed, a 513(g) Request should be submitted, and provides a link to the guidance document.

From [here](#)

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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?

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

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Case Study: Intended Use vs Indications for Use

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Case Study:
Intended Use vs. Indications for Use



Are they the same?
i.e., are they substantially equivalent, are they bioequivalent?

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Case Study: Intended Use vs Indications for Use

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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/implicit 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!

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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 what you say
that matters...***

it's how you say it!

So...

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



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Case Study: Mirrors

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





Five FDA product codes for mirrors:

Product Code	Device	Regulation Number	Device Class
GCO	Endoscope, Mirror	876.1500	2
KAI	Mirror, Ent	874.4420	1
FTX	Mirror, General & Plastic Surgery	878.4800	1
HKF	Mirror, Headband, Ophthalmic	886.1500	1
EAX	Mirror, Mouth	872.4565	1

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

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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)**

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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](#).



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Pathway options:

Wellness

↓

Class I Exempt

↓

Class II
(510k or de novo)

↓

higher?

CFR 880.5780 [here](#)
Product Codes [here](#)

It's all about what you say!

Why do I have to choose...
Can you say label expansion?

(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

1 to 3 of 3 Results
880.5780

Product Code	Device	Regulation Number	Device Class
LLK	Legging_Compression_Non-Inflatable	880.5780	2
FQL	Stocking_Medical_Support_(For_General_Medical_Pur...	880.5780	1
DWL	Stocking_Medical_Support_(To_Prevent_Pooling_Of_B...	880.5780	2

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Using the 510k Database

Product Code Database
↓
510k Database
↓
510k Summary
↓
Review Stats

LLK: [here](#).
FQL: [here](#).
DWL: [here](#).

510(k) Premarket Notification
FDA Home Medical Devices Databases
1 to 4 of 4 Results
Product Code: LLK Decision Date To: 05/16/2018
Results per Page: 10

LLK → 4

Device Name	Applicant	510(k) Number	Decision Date
Ulna-Sleeve(Tm)	Ac Medical, Inc.	K903532	11/02/1990
Tecnot Compression Knee Dressing	Tecnot New Jersey Wound Care, Inc.	K873368	12/11/1987
Comerection Legging Device	A-T Surgical Mfg. Co., Inc.	K871889	08/04/1987

510(k) Premarket Notification
FDA Home Medical Devices Databases
1 to 6 of 6 Results
Product Code: FQL Decision Date To: 05/16/2018
Results per Page: 10

FQL → 6

Device Name	Applicant	510(k) Number	Decision Date
Soft Sock	Silpos, Inc.	K944406	12/27/1994
Elastic Compression Ankle	Orthopaedic Resources Corp.	K823789	01/07/1983
Elastic Compression Ankle	Podiatry Products Corp.	K823350	12/03/1982

510(k) Premarket Notification
FDA Home Medical Devices Databases
1 to 65 of 65 Results
Product Code: DWL Decision Date To: 05/16/2018
Results per Page: 500

DWL → 65

Device Name	Applicant	510(k) Number	Decision Date
Medline Anti-Embolism Stocking	Medline Industries, Inc.	K141127	09/21/2014
Bellavir / Custom Seamless Soft (A.K.A.	Bsn Medical, Inc.	K131496	07/10/2013
Encircle Compression Therapy Stocking	Encircle Medical Devices Ltd.	K122485	04/23/2013

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Is this leg brace a regulated medical device?

Why?
Description
[K151476](#) (Jan, 2016)

BeActive®
The point specific pressure brace for fast effective back pain relief

Special TV OFFER
Now Only **\$19.99** Plus P&H
Just pay \$7.95 P&H for the 1st brace & \$7.95 P&H for the 2nd brace.

ORDER NOW

FDA CLASS 1 MEDICAL DEVICE

Relieves back pain tension with firm pressure
BeActive® is now FDA approved for Class 1 Medical Devices

STEP 2
Align pressure pad at the outer edge of the calf, with the "R" for "right" or "L" for "left" leg facing the front.

ORDER NOW

BeActive® Brace is great for all this:

- **REVOLUTIONARY DISCOVERY:** The patented pressure pad in the brace applies targeted pressure to the specific point that provides back pain relief
- Reduces back pain
- Quick and easy to apply
- Works on either left or right leg
- Discreet and easily hidden under your clothing
- Holds firm and comfortably while exercising or at work

Hiding comfortably under your clothes
Holding firmly in place while you exercise
Helping you live pain free & enjoy being active again

www.beactivebrace.com
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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

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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.

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GreenLight.Guru Webinar (November 24, 2020)

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

For additional information, www.linkedin.com/in/michaeldruess, call (508) 887-9486 or e-mail mdruess@vascularsci.com

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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?

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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?

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Think I'm kidding?

U.S. Food and Drug Administration

FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA

FDA Consumer magazine
September-October 2004 Issue

**Beyond Bloodletting:
FDA Gives Leeches a Medical Makeover**

By Carol Rados

For thousands of years, leeches have been worming their way in and out of medicine as a questionable cure for anything from headaches to gangrene, reaching their height of medicinal use in the mid-1900s. Today, the slimy aquatic creatures are making a comeback as a medical device that can help heal skin grafts and reduce blood clotting. Their primary function is to drain blood. Pooled blood around a wound can cause infection.

In June 2004, the Food and Drug Administration cleared the first application for leeches (*Hirudo medicinalis*) to be used in modern medicine as medical devices. By definition, a medical device is an article intended to diagnose, cure, treat, prevent, or mitigate a disease or condition, or to affect a function or structure of the body, that does not achieve its primary effect through a chemical action and is not metabolized.

Surgeons who do plastic and reconstructive surgery find leeches especially valuable when regrafting amputated appendages, such as fingers or toes. Severe blood clots in such cases often are so damaged that they lack the ability to clear the area of blood. In these cases, it is difficult for the surgeon to make a hole for blood to leave the affected part and return to circulation.

"The idea behind the leeches is to cause blood to ooze so that the body's own blood supply will eventually take over and the limb can go on and survive," says Rod J. Rohrich, M.D., president of the American Society of Plastic Surgeons and chairman of the Department of Plastic Surgery at the University of Texas Southwestern Medical Center. Leeches apply the perfect amount of suction to get the blood flowing. But Rohrich also says he uses the leeches only when there's a compromised situation, such as following surgery, "when the patient's own blood supply isn't adequate."

Packing a one-two chemical punch, the benefit of leech therapy comes not from the amount of blood that is extracted, but in the powerful anti-clotting agent hirudin, contained in the parasite's saliva, which keeps blood flowing freely. At the same time, leeches emit a natural anesthetic that minimizes pain during their feast.

Having disk-shaped suckers on each end of their bodies helps leeches feed, as well as hang on. The number of leeches used varies with each patient—typically two or three leeches are applied to the body until they drop off after about 40 minutes, and then the process is repeated with a new leech "team." At \$7 to \$10 apiece, their expense won't break budgets of physicians or hospitals.

The FDA considered safety data as part of reviewing the marketing application for the leeches submitted by Ricarimex SAS of Eysines, France. In addition, the agency studied published literature on the use of leeches in medicine, how the leeches are fed, their environment, and the personnel who handle them.

Leeches were already being used in hospitals. A 1976 law has allowed companies that raised and sold medical leeches before that year to continue doing so. Newcomers seeking to market leeches for medical purposes, however, were required by the 1976 law to gain FDA approval.

You won't find the type of leeches approved for medical use in a lake, river, or swamp. Rudy Rosenberg, owner and vice president of Leeches USA Ltd., the initial importer and distributor for Ricarimex in the United States, says the leeches are raised under optimum conditions in controlled basins and laboratories. The facilities are certified, and all kits are tracked. This, he says, protects patients from infection. Leeches drop off after "feeding," and must be treated as infectious waste material. Rosenberg says that he knows of no case of leech-borne infection having been reported.

How do people react to being treated with these slimy parasites? "Initially, they're repulsed by the idea of leeches as a treatment," says Rohrich, "but eventually, they come to terms with the fact that it may be saving their lives."

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There are many regulatory consultants out there...
but there are surprisingly few good ones!
So how do you become a good one?

**Learn when to follow and
more importantly...
when to lead!**

**A MAN WHO WANTS TO LEAD THE ORCHESTRA
MUST TURN HIS BACK ON THE CROWD.**

MAX LUCADO

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Don't just follow the rules... think!

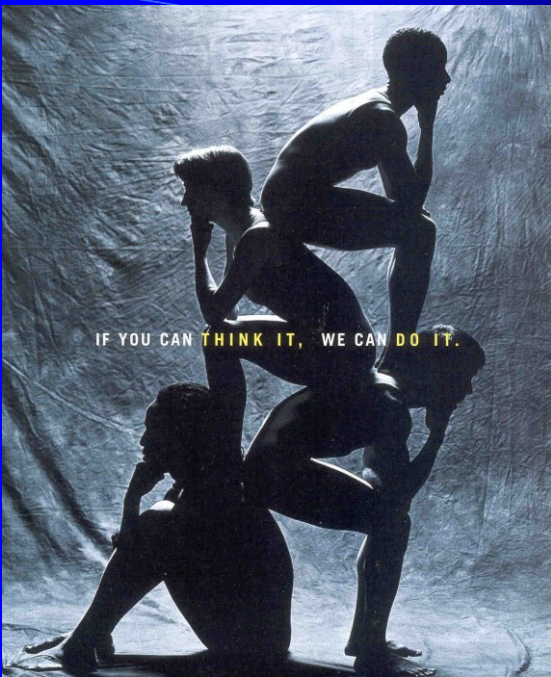


***Rules are mostly made to be broken
and are too often for the lazy to hide behind.***

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.

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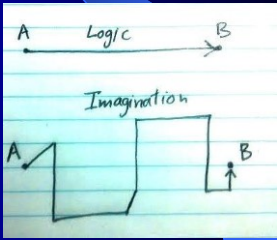
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IF YOU CAN THINK IT, WE CAN DO IT.

"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

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