

# Medical Device Pathways to Market:

*Are You Sure You Know The Best Regulatory Pathway For Your New Medical Device?*

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 (April 2, 2020)**

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

# *Are You Sure You Know the Best Regulatory Pathway for Your New Medical Device?*

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

So you've determined the classification of your medical device or in vitro diagnostic and now it's time to select a regulatory pathway to market. Pretty straightforward decision, right? If your technology is basically the same as an existing device, you choose 510k. If not, then PMA. End of discussion, right?

Not necessarily. Sure, you can follow in the footsteps of the many device makers who have gone before you. Or better yet, you can evaluate all the potential options available and select the path that gives your product the best chance to succeed in an increasingly competitive and challenging market.

In this workshop, we will explore all pathways to market — including the little-known and little-used ones — and discuss how to decide which to use when. Using the case study approach, these questions and others will be presented in an interactive fashion including:

- What are all the pathways to market and the advantages and disadvantages of each?
- How do I decide which one to use and when?
- If my device is class III, is the PMA my only option? If my device is class II, is the 510k my only option?
- How does the *Breakthrough Devices Program* (BDP) and *Safer Technologies Program* (STeP) affect pathway options?
- Can I market a device without any FDA oversight whatsoever?
- If someone else brought a similar device to market using one pathway, must I use the same pathway?
- Must I choose only one pathway? Can I use multiple pathways for the same device at the same time?
- How can I use label expansions to bring my device to market with less time, money and risk?
- How can I get my device on to the market and make it more difficult for my competitors at the same time?
- How do I integrate regulatory strategy with reimbursement strategy, product liability strategy, IP strategy, etc.?

Bottom line: not only are there multiple pathways to market but there advantages and disadvantages to each pathway one. You can combine them, mix and match them, do very interesting things with them... all examples of *competitive regulatory strategy*. So, unless you understand all of the different possible pathways to market for your device — not just the most common ones — and the advantages and disadvantages to each, how can you decide when to use or not use each one? There are many more possibilities than most people think and learning how best to use them is creative regulatory strategy!

What to know more? See:

Podcast: *How to choose the right FDA regulatory pathway for your device* (Feb, 2020) [here](#).

Column: *Are You Sure You Know the Best Pathway for Your New Medical Device?* (MED Device Online [here](#) / podcast [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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### Here's what we'll talk about...

- ✓ What are all the pathways to market and the advantages and disadvantages of each?
- ✓ How do I decide which one to use and when?
- ✓ If my device is class III, is the PMA my only option? If class II, is the 510k my only option?
- ✓ Does *Breakthrough Devices Pgrm* (BDP) and *Safer Technologies Pgrm* (STeP) affect options?
- ✓ Can I market a device without any FDA oversight whatsoever? (wellness exemption)
- ✓ If someone else brought a similar device to market using one pathway, must I use the same?
- ✓ Must I choose only one pathway? Can I use multiple pathways for same device at same time?
- ✓ How can I use label expansions to bring my device to market with less time, money and risk?
- ✓ Can I get my device to market and make it more difficult for my competitors at same time?
- ✓ How do I integrate regulatory strategy with reimbursement, product liability, IP, etc.?
- ✓ **Bonus: can I use the Emergency Use Authorization (EUA) for COVID-19?**
- ✓ Lots more tips and tricks... time permitting!
- ✓ Final thoughts...

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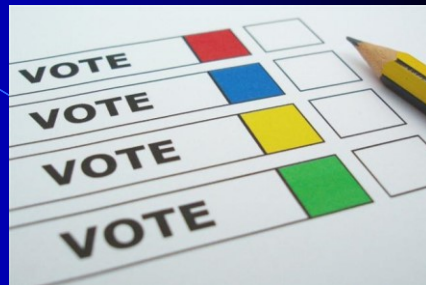


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*Before we begin...*

### Polling Question



- Have you used/are using the 510k?
- Have you used/are using the de novo?
- Have you used/are using the PMA?
- Have you used/are using the EUA?
- Have you used/are using another pathway (in the US)?

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# Breakthrough Device Program:

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



Remember,

***You do not need to take the path most travelled... unless it's to your advantage!***



Short answer:

*There are many of them...  
and there are advantages and disadvantages of each!*

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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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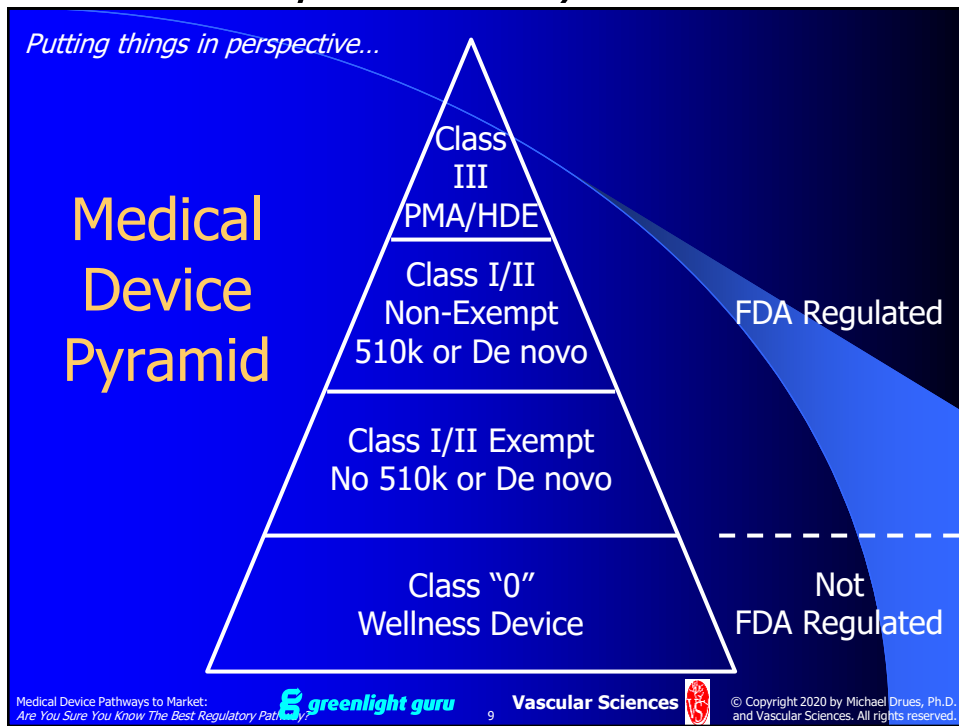
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And now, let's talk about getting a medical device on to the market in the United States...

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## A 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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## What is a general wellness product



Mike's Definition:

A device with 1) “weak” medical claims, 2) “well established” technology and 3) “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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## Bring Medical Devices to Market in the US

Two common choices:

1. Premarket Notification (PMN)  
based on "Substantial Equivalence" (510K)
- or –
2. Investigational Device Exemption (IDE)  
↓  
Premarket Approval (PMA)

When is an IDE 'required' and when is it not? →

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## When is an IDE 'required' and when is it not?



*Many assume a PMA requires an IDE whereas a 510k does not...  
but is that a valid assumption?*

Remember,

*the goal is to understand the regulation – not simply memorize it!*

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## How many 510k devices have clinical data?

**510(k) Premarket Notification**  
FDA Home Medical Devices Databases

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

**Search Database** Help Download Files

510K Number  Type  Product Code

Center  Combination Products ☐

Applicant Name  Cleared/Approved In Vitro Products ☐

Device Name

Panel  Third Party Reviewed ☐

Decision

Decision Date  to  **Clinical Trials** ☒

Sort by  Decision Date (descending)

[Quick Search](#) [Clear Form](#) [Search](#)

Go to the 510k database...  
tick 'Clinical Trials' → 'Search'

Last updated: April 23, 2017 available [here](#).

Result →  
*Does that seem  
small?*  
*Is this a problem?*

**510(k) Premarket Notification**  
FDA Home Medical Devices Databases

11,948 of 346 Results  
**Clinical Trials: Yes Decision Date To:** 04/23/2017

Results per Page 500

[New Search](#) [Export to Excel](#) [Download Files](#) [More About 510\(k\)](#)

Device Name	Applicant	510(K) Number	Decision Date
Coolief® Cooled RF Probe	Halyard Health, Inc.	K163461	04/13/2017
Caresstream Vue Pacs	Caresstream Health, Inc.	K170580	04/11/2017
Pogo Automatic Blood Glucose Monitoring	Intuity Medical, Inc.	K162203	04/06/2017

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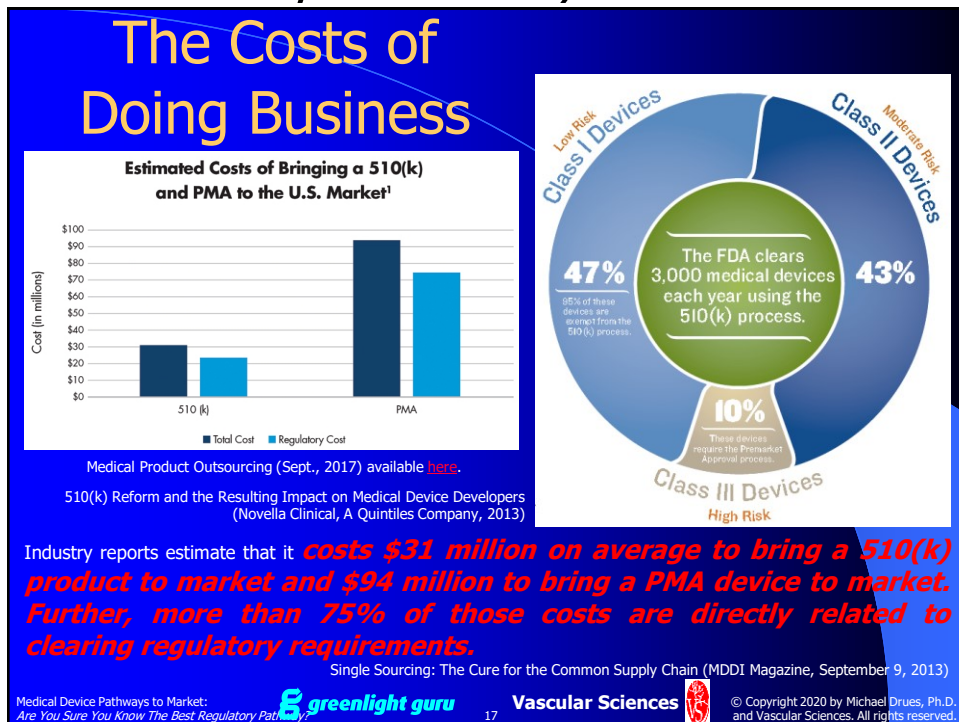
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## What is the PreMarket Notification (PMN) a.k.a. 510k and how can we use it to our advantage

Consider this:

*Many use it but most do not use it well!*

Remember,

70-90% of 510k and PMA submissions are rejected upon first review!

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What are the two most important components of a successful 510k



*Substantial Equivalence Argument  
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## Is there a Governing Equation of the 510k?

Two *fundamental equations* of the 510k are:

$$1) \text{ 510k} = \text{SE} + \text{Risk}$$

and

$$2) \text{ SE} = \text{Labeling} + \text{Technology}$$

To simplify, combining 1) and 2) gives the *Governing Equation of the 510k*:

$$\text{510k} = (\text{Labeling}_{\text{SE}} + \text{Technology}_{\text{SE}}) + \text{Risk}$$

Note: Risk = Risk<sub>Bucket1</sub> + Risk<sub>Bucket2</sub> + Risk<sub>Bucket3</sub>

Simply put, any successful 510k has to solve the equation above i.e.,

valid and defensible solution → 510k

no, invalid or indefensible solution → de novo, PMA...

In other words...

**Don't focus on what the regulation says – focus instead on understanding the *regulatory logic*, i.e., *thinking process*, which is infinitely more important than regulation!**

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The premarket notification, a.k.a. the 510k, is the most common pathway used to bring new medical devices to market in the US.

Yet despite FDA issuing multiple guidance's since the 510k was created in 1976, **75% of 510k's are rejected** (i.e., via "additional information" requests) and of those that are rejected, **nearly 85% are rejected specifically because of substantial equivalence or the lack thereof**.

Simply put, no 510k should ever be rejected – and **certainly not due to substantial equivalence** – this is an **amateur mistake** (see MOUFA [link](#)).

Such delays and rejections result in obvious increases in time and cost to market – many of which could be minimized or avoided!

One area receiving regulatory scrutiny is the substantial equivalence (SE) argument. Simply put without a strong substantial equivalence argument, your 510k submission will not be successful. And if FDA says your device is not substantially equivalent (NSE), does it mean your device is in fact NSE?

Not necessarily! But what does SE really mean and how do I show it? How do I use not just what the regulation says but also what it does not say to my advantage?

Using the case study approach, these questions and others will be presented in an interactive fashion.

**SPECIFICALLY THIS WEBINAR WILL COVER:**

- Understand the regulatory requirements of substantial equivalence and how to use them to your advantage

**PRESENTER**

Michael Drues, Ph.D.  
President  
Vascular Sciences

**MODERATOR**

Jim Smith  
Founder & VP QA/RA  
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### UNDERSTANDING THE MANY CONNOTATIONS OF RISK IN MEDICAL DEVICE DEVELOPMENT AND THE CONSEQUENCES OF GETTING THEM WRONG

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presented by:

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President, Vascular Sciences, Grafton, Massachusetts

Adjunct Professor of Regulatory Science, Medicine, and Biomedical Engineering

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*When is a PMA required?*

If a device is class III,  
must we do a PMA



**Nope!**

HDE: medically plausible subset (<8K) / efficacy vs. "probable benefit"  
PDP – "well established technology"


Both can be used as a label expansion later → bigger market

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Once a device gets to  
market via a PMA, can  
another company do a  
510k using the same  
device?



Textbook answer: *no but the textbook is never complete!*  
Mike: *theoretically possible – how?*

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Can we use a predicate  
for a PMA



*No concept of substantial equivalence... or is there?*

Mike: Testing Matrix + Risk

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How to decide whether to  
use the PMA or another  
pathway to market

When a PMA is preferred  
over a 510k



Think *competitive regulatory strategy!*

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# Breakthrough Device Program:

## *Is this an option for my medical device?*

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Guest Column | May 13, 2014

### FDA's PMA Pathway: Friend Or Foe?

By Michael Drues, Ph.D., President, Vascular Sciences

Approximately 10% of all medical devices enter the U.S. market through the FDA's premarket approval (PMA) process, making it the second most-used U.S. pathway behind the 510(k). Since the PMA path is required for devices that are high risk (Class III) or for which no predicate exist, it is much more rigorous – that is to say, more complex and time consuming – than the 510(k).

Despite its onerous reputation, the PMA may actually be the most advantageous pathway for your device, and there are changes afoot within the agency that should help make the PMA path less forbidding for manufacturers.

**Advantages Of PMA**

Although it is the most burdensome pathway to market for medical devices – requiring more in-depth benchtop testing and often computational testing, animal testing, and human clinical trials – there are several advantages of pursuing PMA.

Say you're bringing a new device onto the market, and it's in that nebulous or gray area between the 510(k) and the PMA. It could go either way. Many companies would be tempted to simply take the 510(k) route, because it is the quickest, least risky, and least expensive way to get a medical device onto the market. However from a competitive perspective, you might be wise to consider setting the bar a little bit higher in going the PMA route.

Why? Yes, it will make your job a little more difficult. On the other hand, it will make the job more difficult for your competition as well.

So, if you're working for a large medical device company and your competition is a small company or startup, it actually might be to your advantage to set the FDA bar higher. This creates a sort of speed bump in the road, so to speak, causing your competition to really question whether or not they want to follow you. This is a technique I call competitive regulatory strategy. In my experience, most regulatory folks never think in these terms.

**New PMA Guidelines**

The FDA recently released two draft guidance documents that might make the PMA pathway even more desirable for device makers.

**YOU MAY ALSO LIKE...**

**Secrets Of The De Novo Pathway, Part 1: Why Aren't More Device Makers Using It?**  
The de novo classification option, introduced as part of the U.S...

**Secrets Of The De Novo Pathway, Part 2: Is De Novo Right For Your Device?**  
In Part 1 of this series, we explored the history of the FDA's de novo classification – what it is, why it was established, why it has been underutilized by medical device makers, and what the agency has done in recent years to make it...

**3D Printing In Medicine: 4 Questions That Need To Be Answered**  
Almost everyone would agree that 3D printing has a bright future in the medical device industry. So what's holding it back? This article poses four questions the industry must answer before 3D printing can reach its full potential in...

**The Premarket Approval Pathway: Ensure Successful Regulatory Submissions**  
Wednesday, June 4, 2014 4pm - 5:30pm EDT 90 Minutes

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Podcast | May 19, 2014

### Why You Should Choose The FDA's PMA Pathway Over The 510(k)

Most manufacturers of Class I and Class II medical devices seek to avoid the FDA's premarket approval (PMA) pathway at all costs, opting instead for the kinder, gentler, and faster 510(k) route. But is that the right approach for *your* device? Believe it or not, the dreaded PMA can actually be your ally in regulatory strategy, helping make it more difficult for your competitors to bring similar products to market. In this podcast, Med Device Online's Jim Pomager talks with Vascular Sciences' Mike Drues about the ways in which the PMA path can actually benefit device makers – and about recent FDA guidance that could make the PMA less ominous.

00:00 00:00

Embed

**\*\*For those of you interested in further information about the PMA pathway, Dr. Drues will be teaching an online course entitled The Premarket Approval Pathway: Ensure Successful Regulatory Submissions. The 90-minute course will be presented by Life Science Training Institute on June 4, 2014, at 1 pm EDT time. For more information or to register, visit [here](#).**

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The image shows a promotional banner for a webinar. At the top left is the 'greenlight guru' logo in green. Below it, the text reads 'Free Live Webinar by greenlight guru + VASCULAR SCIENCES'. The main title of the webinar is 'THE PRE-MARKET APPROVAL (PMA): IS IT REALLY AS BAD AS SO MANY THINK?' in purple and white. A purple button says 'REGISTER NOW→'. The date and time are 'SEP 6TH @ 1:00PM ET/ 10:00AM PT'. On the right, there are two circular headshots. The top one is for 'MICHAEL DRUES PH.D., President Vascular Sciences'. The bottom one is for 'JON SPEER Founder & VP QA/RA Greenlight Guru'. At the bottom of the banner, there is a URL 'www.greenlight.guru/webinar/pre-market-approval' and logos for 'greenlight guru' and 'Vascular Sciences'. A small copyright notice at the bottom right says '© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.'

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The image is a blue slide with white and yellow text. The title is 'Additional Pathways to Market' in yellow. Below it, in white, are 'Product Development Protocol (PDP)', '– and –', 'de Novo pathway', '– and –', 'Humanitarian Use Device (HUD) ⇒ Humanitarian Device Exemption (HDE)', '– and –', 'Custom Device Exemption (CDE)', '– and –', and 'Emergency / compassionate use situations'. At the bottom, it says 'Bottom line: Although seldomly used, Unless you understand all possible pathways and the advantages and disadvantages of each, how can you know when to use (or not use) each one? i.e., how can you do your job?'. The footer includes the 'greenlight guru' logo, 'Vascular Sciences' logo, and a copyright notice: '© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.'

**Additional Pathways to Market**

Product Development Protocol (PDP)

– and –

de Novo pathway

– and –

Humanitarian Use Device (HUD) ⇒ Humanitarian Device Exemption (HDE)

– and –

Custom Device Exemption (CDE)

– and –

Emergency / compassionate use situations

Bottom line: Although seldomly used,  
*Unless you understand all possible pathways and the advantages and disadvantages of each, how can you know when to use (or not use) each one? i.e., how can you do your job?*

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## *Is this an option for my medical device?*

### Product Development Protocol (PDP)

- ✓ sub-type of PMA... technically
- ✓ ideal candidates are devices where technology is 'well established'
- ✓ PDP is essentially a contract (i.e., a meeting of the minds) that allows sponsor to reach early agreement with FDA concerning how to demonstrate safety and effectiveness of new device
- ✓ Manufacturer can move forward at their own pace and when the PDP has been declared completed by FDA, it's considered to have an approved PMA.

#### Recommendations:

- ✓ if you're developing a class III device using a technology that has been around for a while, this seldom used pathway is worth a look
- ✓ for everyone else, consider this:

*When thinking of the PDP as a contract i.e., a meeting of the minds, it is no different than any other pathway to market – an understanding as to what will be done from the beginning will save a lot of time and headache in the end!*

See CDRH website 'PMA Application Methods' available [here](#).

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## Want to understand the de novo



*Think Band-Aids!*

*Why?*

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# Breakthrough Device Program:

*Is this an option for my medical device?*

Could the de novo be simpler than the 510k



Short answer: yes

*Why?*

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What are the two most important components of a successful 510k



*Substantial Equivalence Argument  
and Risk Mitigation Strategy*

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# What's the biggest advantage of the 'de novo' compared to the 510k



*You're starting out with a blank canvas and you can paint on to it anything you would like – assuming you can support it that is!*

Who can explain?

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# What does blank canvas mean?

**Product Classification**  
FDA Home Medical Devices Databases

New Search Back To Search Results

Device Tubes, Vials, Systems, Serum Separators, Blood Collection  
Regulation Description Blood specimen collection device.  
Regulation Medical Specialty Clinical Chemistry  
Review Panel Clinical Chemistry  
Product Code JKA  
Premarket Review Center for [Biologics Evaluation & Research](#) (CBER)  
Submission Type 510(k)  
Regulation Number [862](#) [1675](#)  
Device Class 2  
Total Product Life Cycle (TPLC) [TPLC Product Code Report](#)  
GMP Exempt? No

Recognized Consensus Standards

- CLSI N8201-A6 Blood Collection on Filter Paper for Newborn Screening Programs, Approved Sixth Edition
- CLSI GP39-A Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection, Approved Guidance
- CLSI GP39-A4 (Formerly H11-A4) Procedures for the Collection of Arterial Blood Specimens, Approved Guidance
- CLSI GP39-A5 (Formerly H11-A5) Procedures for the Collection of Venous Blood Specimens, Approved Guidance
- CLSI GP39-A6 (Formerly H11-A6) Tubes and Additives for Venous Blood Specimen Collection, Approved Standard-Sixth Edition

Implanted Device? No  
Life-Sustain/Support Device? No  
Third Party Review  

- Eligible for [Accredited Persons Expansion Pilot Program](#)

  
Accredited Persons

- Desira Certification B.V.
- Regulatory Technology Services, Ltd.
- Taxi Sud America, Inc.

With a 510k you start with this and you must fit in someone else's box...

# Which would you choose?

With a de novo you start with this and others must fit in your box!

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Advanced Strategies and Tactics for Using the De Novo Pathway

presented by:

**Michael Drues, Ph.D.**

President, Vascular Sciences, Grafton, Massachusetts

Adjunct Professor of Regulatory Science, Medicine, and Biomedical Engineering

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## What is the Humanitarian Device Exception (HDE) and when should it be used



*The medical equivalent of the orphan drug program.*

*Although there are limitations, there are some significant advantages!*

i.e., lower regulatory burden (efficacy), label expansion, others...

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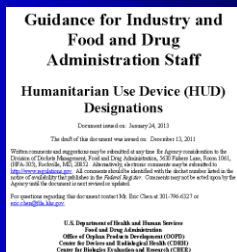
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## What is the HUD/HDE?

- ✓ Similar to orphan drug program
- ✓ Limited to 8000 patients / year – 'medically plausible subset'  
*Numbers can be added up in many different ways!*
- ✓ No efficacy requirement – 'probable benefit'
- ✓ Profit limitation ??
- ✓ Not a lot of 'regulation' – huge advantage!
- ✓ Think label expansion – HDE now... something else later



Humanitarian Use Device (HUD) Designations  
(CDRH Guidance, January, 2013)

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### Humanitarian Device Exemption (HDE) Program

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

Document issued on September 6, 2019.

The draft of this document was issued on June 13, 2018.

For questions about this document regarding CDRH-regulated devices, contact OOPD, Office of Regulatory Programs (ORP), Division of Submission Support, Center for Devices and Radiological Health, at 301-796-5440.

For questions about this document regarding CDRH-regulated devices, contact OOPD, Office of Regulatory Programs (ORP), Division of Submission Support, Center for Devices and Radiological Health, at 301-796-5440.

This guidance supersedes "Guidance for HDE holders, Institutional Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff, Humanitarian Device Exemptions (HDE) Regulations: Qb Answers," issued July 8, 2010.

An agency may not conduct or sponsor, and a person is not required to respond to, unless it displays a currently valid OMB control number. The OMB control number collection is 0910-0061 (expires 09-30-2019).

See additional FDA statement in Section IX of this guidance.

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Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Orphan Products Development (OOPD)  
Center for Devices and Radiological Health (CDRH)  
Center for Biologics Evaluation and Research (CBER)

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For questions regarding this document contact Dr. Enika Torjussen at 301-796-2278 or [Enika.Torjussen@FDA.HHS.gov](mailto:Enika.Torjussen@FDA.HHS.gov).

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Food and Drug Administration  
Office of Orphan Products Development (OOPD)  
Center for Devices and Radiological Health (CDRH)  
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## HDE Guidance

Guidance: [Humanitarian Device Exemption \(HDE\) Program \(Sept, 2019\)](#) [here](#)  
 Guidance: [Humanitarian Use Device \(HUD\) Designations \(Sept, 2019\)](#) [here](#)  
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# Breakthrough Device Program:

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### Changes to HDE from the

21st Century  
Cures Act



Minor changes to HDE were part of *Cures Act*, i.e.,

- must demonstrate HUD “will not expose patients to an *unreasonable or significant risk* of illness or injury” – *what does that mean?* (not new)
- very little-to-no profit in most cases – *is that an incentive?* (not new)  
No similar limitation for drugs! – *why?*
- remove IRB oversight limitation – *is this a good idea?*
- “fewer than 4k” → “not more than 8k” – *will that make a difference?*  
What is the comparable limitation for orphan drugs?

The question is:

***Will any of these changes significantly affect the regulatory burden and/or the attractiveness of the HDE program? i.e., will these changes increase the popularity of the program?***

***How much of this is pure politics? i.e., sound bytes vs. reality?***

FDA Amends Humanitarian Device Exemption Regulations (RAPS, June 6, 2017 [here](#)).

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### How would you bring this device to market?



Case Study: transcatheter pulmonary heart valve

510k – not likely (based on risk)

PMA – could but is there another way?

HDE – what would you need to show?

Identify ‘medically plausible subset’ of <8000 (4K at the time) patients per year – *how?*

Congenital Heart Disease is most common birth defect affecting ~40K babies/year – *that’s to many!*

~20% have deformities from their right ventricular outflow tract to the pulmonary arteries

Recommendation:

*Continue to limit intended patient population via labeling until numbers add up to <4000*

Medtronic Melody Transcatheter Pulmonary Valve Wins FDA PMA Approval (Med Gadget, Feb 3, 2015) available [here](#).

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# Breakthrough Device Program:

## *Is this an option for my medical device?*

**Medical Devices**

Home Medical Devices Products and Medical Procedures Device Approvals and Clearances Recently-Approved Devices

**Products and Medical Procedures**

Device Approvals and Clearances

Recently-Approved Devices

2015 Device Approvals

2014 Device Approvals

### Medtronic Melody® Transcatheter Pulmonary Valve - H080002

#### New Humanitarian Device Approval

FDA approved this device under the Humanitarian Device Exemption (HDE) program. See the links below to the Summary of Safety and Probable Benefit (SSPB) and other sites for more complete information on this product, its indications for use, and the basis for FDA's approval.

**Product Name:** Medtronic Melody® Transcatheter Pulmonary Valve (Model PB10) and Medtronic Ensemble® Transcatheter Valve Delivery System (NU10)

**Manufacturer:** Medtronic Heart Valves, Inc.

**Address:** 1851 Deere Avenue, Santa Ana, California 92705

**Approval Date:** 25 January 2010

**Approval Letter:** [http://www.accessdata.fda.gov/cdrh\\_docs/pdf9/H080002a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf9/H080002a.pdf)

**What is it?**

The Medtronic Melody® Transcatheter Pulmonary Valve is a manufactured replacement pulmonary heart valve that had already been previously repaired. The pulmonary valve is one of four valves in the human heart that help pump blood throughout the body. The Melody valve is made from a cow's jugular vein valve that is sewn into a small metal stent (scaffolding). The Melody valve comes in sizes 18, 20, and 22mm diameters and has a stent length of 28mm. The Medtronic Ensemble® Transcatheter Valve Delivery System is a catheter (long tube with small diameter) that helps guide the Melody into the heart. The Ensemble delivery system has catheters with balloon sizes of 18, 20, and 22mm.

**How does it work?**

The Melody heart valve is first crimped down onto the Ensemble delivery catheter's balloon and then is fished through a vein in the groin and into the right side of the heart where it is placed into position within the pulmonary valve. The small balloon is then inflated to open up the Melody valve into position, the catheter is removed from the body, and the Melody immediately becomes the new pulmonary valve.

**When is it used?**

The Melody is used to repair a stenosed (blocked) or regurgitant (leaky) pulmonary heart valve that has previously been replaced to correct congenital (birth) heart defects. The Melody is put in place without using open heart surgery and while the heart is beating.

**What will it accomplish?**

The Melody will replace a poorly functioning, previously replaced pulmonary valve in children and adults who might otherwise need multiple open heart surgeries in their lifetime. The Melody will repair pulmonary valve function without open heart surgery and may lengthen the time until a patient needs additional open heart surgery.

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## Label Expansion: HDE → PMA



Now you want to go after a bigger market?

*PMA based on accumulated data from three post-approval studies (310 patients)*

Remember,

***Label expansions ALWAYS easier than getting product on market first time!***

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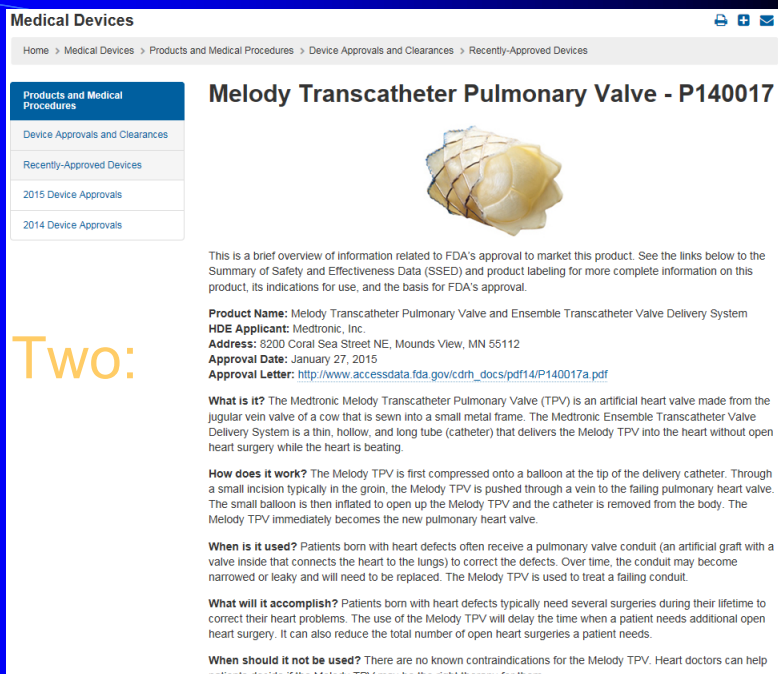
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# Breakthrough Device Program:

## *Is this an option for my medical device?*

## Step Two:



**Medical Devices**

Home > Medical Devices > Products and Medical Procedures > Device Approvals and Clearances > Recently-Approved Devices

**Melody Transcatheter Pulmonary Valve - P140017**

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

**Product Name:** Melody Transcatheter Pulmonary Valve and Ensemble Transcatheter Valve Delivery System  
**HDE Applicant:** Medtronic, Inc.  
**Address:** 8200 Coral Sea Street NE, Mounds View, MN 55112  
**Approval Date:** January 27, 2015  
**Approval Letter:** [http://www.accessdata.fda.gov/cdrh\\_docs/pdf4/P140017a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf4/P140017a.pdf)

**What is it?** The Medtronic Melody Transcatheter Pulmonary Valve (TPV) is an artificial heart valve made from the jugular vein valve of a cow that is sewn into a small metal frame. The Medtronic Ensemble Transcatheter Valve Delivery System is a thin, hollow, and long tube (catheter) that delivers the Melody TPV into the heart without open heart surgery while the heart is beating.

**How does it work?** The Melody TPV is first compressed onto a balloon at the tip of the delivery catheter. Through a small incision typically in the groin, the Melody TPV is pushed through a vein to the failing pulmonary heart valve. The small balloon is then inflated to open up the Melody TPV and the catheter is removed from the body. The Melody TPV immediately becomes the new pulmonary heart valve.

**When is it used?** Patients born with heart defects often receive a pulmonary valve conduit (an artificial graft with a valve inside that connects the heart to the lungs) to correct the defects. Over time, the conduit may become narrowed or leaky and will need to be replaced. The Melody TPV is used to treat a failing conduit.

**What will it accomplish?** Patients born with heart defects typically need several surgeries during their lifetime to correct their heart problems. The use of the Melody TPV will delay the time when a patient needs additional open heart surgery. It can also reduce the total number of open heart surgeries a patient needs.

**When should it not be used?** There are no known contraindications for the Melody TPV. Heart doctors can help patients decide if the Melody TPV may be the right therapy for them.

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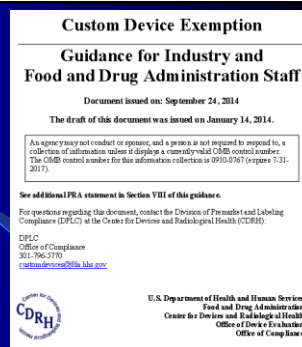
## Custom Device Exemption (CDE)

Custom Medical Device Exception Guidance (CDRH, September 24, 2014) available [here](https://www.fda.gov/oc/ohrt/cde-guidance).

- ✓ Least commonly used pathway to market
- ✓ Historically used for dental appliances, prescription glasses and prosthetic limbs
- ✓ In future, CDE has potential to become just as popular, if not more popular, than the 510(k)!
- ✓ Warning: step carefully when travelling down this path.

Recently an orthopedics manufacturer announced it would discontinue its custom orthopedics in response to a CDRH warning letter saying certain custom devices would need new PMA or 510(k) applications. A few days later the company announced it would permanently stop production of all custom devices, not just those listed in the warning letter. So now what happens to the patients with no options – like in politics, power voids don't last long so can you say off-label use?

- ✓ Nonetheless, because the CDE is so uncommonly used, there is little written regulation on it and that, in and of itself, is a huge advantage to me!



**Custom Device Exemption**  
**Guidance for Industry and Food and Drug Administration Staff**  
 Document issued on: September 24, 2014  
 The draft of this document was issued on January 14, 2014.

An agency may not conduct an inspection, 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 0910-0767 (expires 7-31-2017).

See additional FDA statement in Section VII of this guidance.

For questions regarding this document, contact the Division of Premarket and Labeling Compliance (DPLC) at the Center for Devices and Radiological Health (CDRH).

DPLC  
 Office of Compliance  
 301-796-3770  
[cdreh@fda.hhs.gov](mailto:cdreh@fda.hhs.gov)

U.S. Department of Health and Human Services  
 Food and Drug Administration  
 Center for Devices and Radiological Health  
 Office of Device Evaluation  
 Office of Compliance

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Case Study: [From Medical Device Exemption \(CDE\)](#)

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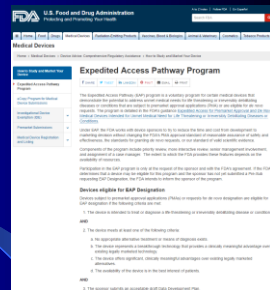
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## Expanded Access Pathway

- ✓ a.k.a. compassionate use or emergency use
- ✓ allows use of an investigational medical product (i.e., device/drug/etc. not approved/cleared by FDA) *outside of clinical trial* in situations where patient has few if any alternatives and is usually in eminent demise
- ✓ although there are often ethical considerations, it may be appropriate to consider this option as a way to get early feasibility data for high risk devices, especially when suitable animal models are unavailable
- ✓ like the HDE/orphan designation, this data could then be used to expand the label later



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## Are there faster ways to market



*Are there shortcuts?*

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# Breakthrough Device Program:

## *Is this an option for my medical device?*

### "Accelerated" Pathway Option Comparison

	Priority Review Program (PRP)	Expedited Access Program (EAP)	Breakthrough Devices Program (BDP)
<b>Eligibility</b>	Device that provides for <i>more effective</i> treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and meets one of the following criteria: <ol style="list-style-type: none"> <li>1. Represents a breakthrough technology,</li> <li>2. No approved alternatives exist,</li> <li>3. Offers significant advantages over existing approved alternatives, or</li> <li>4. The availability of which is in the best interest of the patients.</li> </ol>		
<b>Applications Accepted</b>	PMA, DeNovo, 510(k), PDP	IDE, PMA, DeNovo <sup>1</sup>	Q-Sub, IDE, PMA, DeNovo, 510(k) <sup>2</sup>
<b>Interactive Review</b>	No	Yes	Yes
<b>Sr. Management Involvement</b>	No	Yes	Yes
<b>Sprint Discussions</b>	No	No	Yes
<b>Data Development Plan(DRD)</b>	No	Yes	Not mandated
<b>Clinical Protocol Agreement</b>	No	No	Yes
<b>Regular Status Updates</b>	No	No	Yes
<b>When to submit request for designation</b>	At time of marketing application	Included in a Q-Sub, preferably prior to IDE pivotal study.	Before submission of a marketing application. Requests should be made in a separate Q-Sub
<b>FDA timeframe for granting/rejecting request</b>	<ul style="list-style-type: none"> <li>• 510(k) or DeNovo = 14 days within receipt of submission</li> <li>• PMA: during the 45 days filing review</li> </ul>	Within 30 days of receipt <sup>3</sup>	Within 60 days of receipt
<b>Review Time</b>	Eligible applications will be placed at the beginning of the review queue. PRP applications reviewed on a first-in/first-reviewed basis.	PMAs with EAP designation receive Priority Review. De novo requests with EAP designation - FDA intends to make a determination in less than 120 days	Same as PRP

<sup>1</sup> Not all provisions of the EAP are applicable to DeNovo applications.

<sup>2</sup> Includes combination products under the device pathway.

<sup>3</sup> If there is insufficient information for FDA to make a decision, FDA may request the sponsor submit additional information. If additional information is not received within 30 days, FDA may reject the request.

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Are You Sure You Know The Best Regulatory Pathway?



Breaking Through FDA's New "Accelerated" Pathway

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(MDDI, May 29, 2018) <http://www.vascsci.com>  
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## What is the Breakthrough Devices Program and why does it exist



*Incentivize companies to develop "important" devices **AND** to "encourage" FDA to get them to market more efficiently.*

Note: BDP is not a pathway to market, i.e., BDP ≠ 510k, de novo, PMA, HDE, etc.

Note: not an excuse to take shortcuts... **regulatory burden remains unchanged!**

*Does it work in reality? Depends who you ask!*

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## *Is this an option for my medical device?*

### Breakthrough Designation Program Justification

The purpose of this section is to provide an explanation and justification as to why the <DEVICE NAME> currently under development qualifies for breakthrough device designation status defined under the 21st Century Cures Act and the *Breakthrough Devices Program Guidance* (December, 2018) [here](#).

To qualify for BDP status, the device under consideration must meet the following criteria:

1. PMAs, 510[k] and De Novo devices eligible for EAP designation if:
  - the device provides for more effective **treatment/diagnosis** of life-threatening/irreversibly debilitating disease/condition – *where is prevention?*
- AND
2. the device meets at least one of the following criteria:
  - device represents 'breakthrough technology'
  - no approved/cleared alternatives exist (i.e., is there an "unmet clinical need?")
  - offer clinically meaningful advantages over existing approved/cleared alternatives (i.e., ↓ hospitalization, ↑ quality of life, etc.)
  - availability of device is in the best interest of patients (i.e., put a face on the problem)

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**REGISTER NOW →**

July 18th @ 1:00p ET / 10:00a PT


[www.greenlight.guru/webinar/breakthrough-designation-program-option-for-medical-devices](http://www.greenlight.guru/webinar/breakthrough-designation-program-option-for-medical-devices)

**Presenter**



**MICHAEL DRUES, PH.D.**  
President at Vascular Sciences

**Moderator**



**JESSECA LYONS**  
Senior Medical Device Guru at Greenlight Guru

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*What if my device is "safer" but not necessarily more effective?*

## Safer Technologies Program for Medical Devices (STeP)



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## More about STeP

### Medtech Matters

Beyond 510(k)/PMA—Safer Technologies Program

OCTOBER 16, 2019 EPISODE 34



00:00 | 24:25

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#### SHOW NOTES

In this Medtech Matters podcast episode of Mike on Medtech with Mike Drues, president of Vascular Sciences, we discuss the brand new (in fact, yet-to-be-launched) Safer Technologies Program (click to review the guidance). Since it was only recently introduced, there are still a number of questions device manufacturers have about the program. With this in mind, we thought it would be a great topic to cover as part of this

Podcast: **Mike on Medtech: Safer Technologies Program** (MPO Magazine, Oct. 16, 2019) [here](#)

Additional sources of Information:

- RAPS Article: **Not Quite a Breakthrough Device, FDA Introduces New Safer Technologies Program** (RAPS, Sept 18, 2019) [here](#).
- FDA Guidance: **Safer Technologies Program for Medical Devices** (Sept, 2019) [here](#).
- Article: **FDA Proposes Safer Technologies Program For Medical Devices** [here](#).

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### IS FDA'S NEW 'SAFER TECHNOLOGIES PROGRAM' APPLICABLE TO YOUR MEDICAL DEVICE?

By Nick Toomarian, October 16, 2019. In Global Medical Device Podcast and Risk Management and Regulatory Affairs and Mike Drues and Medical Device Industry



Podcast: **Is FDA's new "Safer Technologies Program" applicable to your medical device?** (Greenlight.Guru, Oct. 2019) available [here](#).

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# Breakthrough Device Program:

## *Is this an option for my medical device?*



**Emergency Use Authorization**  
Emergency Use Authorization (EUA) information, and list of all current EUAs

Emergency Use Authorization (EUA) [here](#)

**What is the emergency use authorization (EUA)?**

"allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological and nuclear defense threats by facilitating the availability and use of **medical countermeasures** needed during public health emergencies."

**"may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives."**

EAU Previously used: Anthrax, Ebola Virus, H7N9 Influenza, Zika Virus, a few others

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**Similar guidance's now for "limited" number of other "critical" devices.**

**What about modifications to existing devices (i.e., devices already on market for something else)?**

Guidance: *Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019* (Mar, 2020) [here](#)

Purpose: non-invasive remote monitoring devices to facilitate patient monitoring while reducing patient and healthcare provider contact and exposure

Duration: **remain in effect only for the duration of the public health emergency**

Disclaimer: FDA **does not intend to object to limited modifications** to the indications, claims, functionality, or hardware or software of **[an already] FDA cleared** non-invasive remote monitoring devices that are used to support patient monitoring **during the declared public health emergency**

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**Emergency Use Authorization**  
Emergency Use Authorization (EUA) information, and list of all current EUAs

Emergency Use Authorization (EUA) [here](#)

**Does EUA lower the regulatory burden compared to other pathways to market?**  
According to FDA... YES (e.g., hand sanitizers, PPE, i.e., face masks, etc.), but should it?  
Waving FDA Registration?  
– *Ok but... still should meet quality requirements, design controls, etc.*  
Waving GMP Requirements?  
– *Absolutely not... will likely cause more problems than it solves!*  
**EUA should be similar to BDP... same regulatory burden but more efficient path to market!**

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## Where is the balance?



**MD+DI Qmed**  
MEDICAL DEVICE AND DIAGNOSTIC INDUSTRY

Topics Qmed Directory Events

**FDA Warns Against Fraudulent COVID-19 Tests and Treatments**  
The agency's warning comes at a time when there are 61,062 COVID-19 cases reported in the U.S., with 838 deaths, and 387 recovering.

By Omar Ford  
March 25, 2020 in *Regulatory and Compliance*

**Thus far FDA has issued almost as many warning letters as EUA's!**  
FDA Warns Against Fraudulent COVID-19 Tests and Treatments [here](#)

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## Haste makes Waste... or Worse?

"LA County got 170 broken ventilators from feds... silicon valley is fixing them."  
LA Times, March 30, 2020 [here](#).

***This was 100% predictable!***

So what's worse?

***Not having enough ventilators...***

OR

***Having a bunch of ventilators that don't work?***

Is it possible to have enough ventilators that work?

***Absolutely YES!***

Take-aways:

- ✓ Importance of having a *good* QMS
- ✓ One would like to think QC tested ventilators before releasing to hospitals
- ✓ Suffocating 179 patients using malfunctioning ventilators would not a mistake I would want to make!
- ✓ Personal e-mails from FDA expressing concerns

News Video: Can Tesla, GM And Ford Help Solve The Coronavirus Ventilator Shortage? (CNBC, Mar 27, 2020) [here](#)


FDA Ventilator EAU Letter [here](#) (3/24/20)

Medical Device Pathways to Market:  
*Are You Sure You Know The Best Regulatory Pathway?*

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## What are some more 'interesting' (advanced?) regulatory strategies

*This is just the beginning!*

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[www.greenlight.guru/webinar/are-you-sure-you-know-the-best-regulatory-pathway-for-your-new-medical-device](http://www.greenlight.guru/webinar/are-you-sure-you-know-the-best-regulatory-pathway-for-your-new-medical-device)

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

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# Breakthrough Device Program:

*Is this an option for my medical device?*

Must I use only one regulatory pathway



Short answer: *absolutely not!*  
i.e., proprietary regulatory strategy

Case Study: *Magoo*

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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)

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

Plus:

Breakthrough Devices Program (BDP) and Safer Technologies Program (STeP)  
BDP and STeP are not pathways *per se* but certainly worth considering

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# Breakthrough Device Program: *Is this an option for my medical device?*

There are many pathways to market...

*Many more than drugs!*

And it can be confusing...



But...

*Must we take the path most taken?*

*Must we choose only one?*

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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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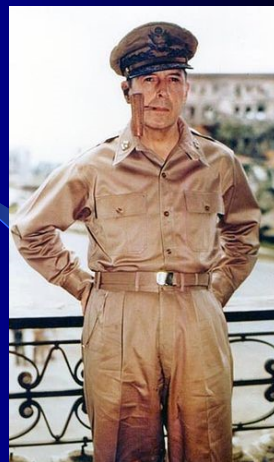
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# Breakthrough Device Program:

## *Is this an option for my medical device?*

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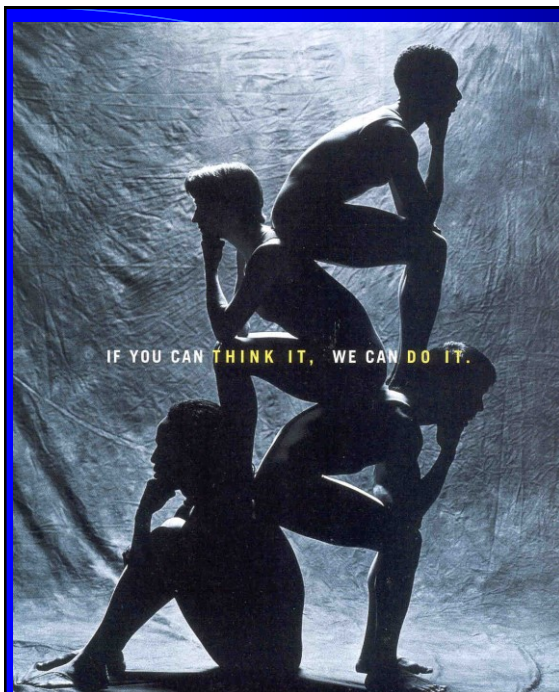
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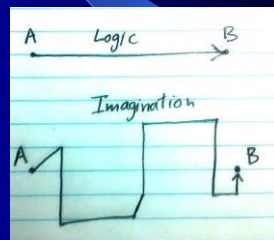
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"Imagination is more important than knowledge, for while knowledge points to all there is, imagination points to all that can be."

Albert Einstein



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

Albert Einstein

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