Medical Device Pathways to Market:

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

Presented by:

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and

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Cornell University Graduate Dept. of Biomedical Engineering

GreenLight.Guru Webinar (April 2, 2020)
www.greenlight.guru/webinar/are-you-sure-you-know-the-best-regulatory-pathway-for-your-new-medical-device

For questions or more information, call
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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.

Breakthrough Device Program:

Is this an option for my medical device?

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Breakthrough Device Program:

Is this an option for my medical device?

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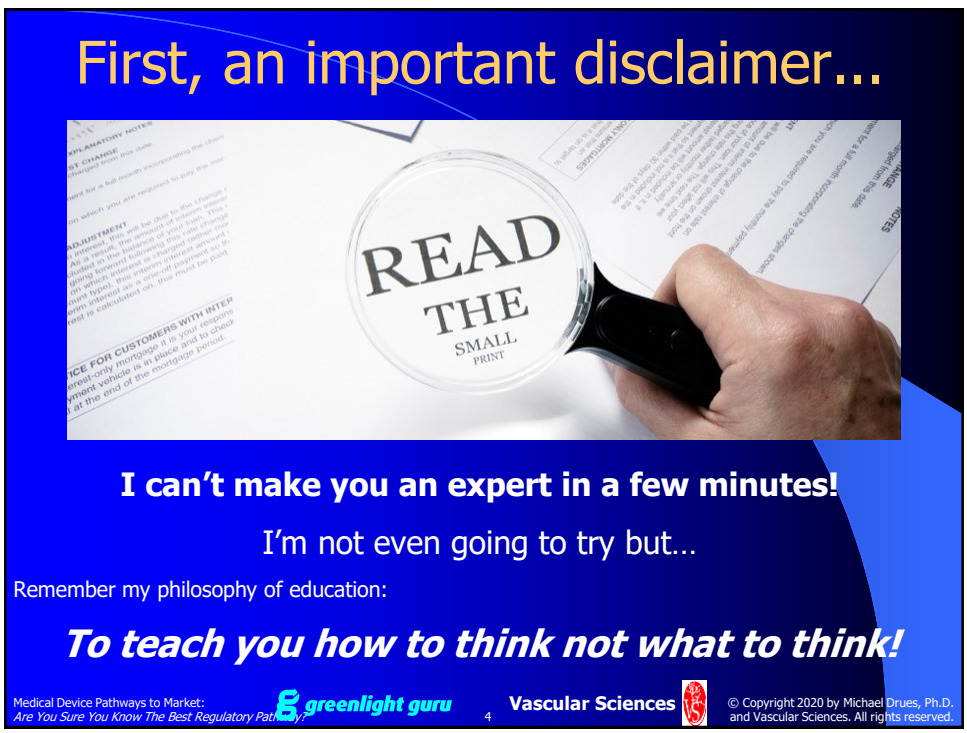

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Breakthrough Device Program:

Is this an option for my medical device?

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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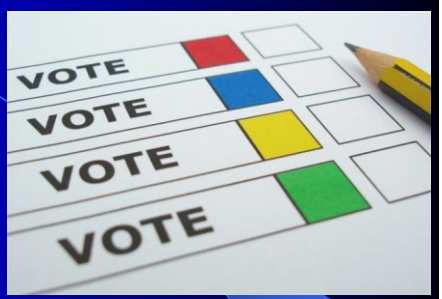
Before we begin…

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:

Is this an option for my medical device?

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 <u>most</u> 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)

…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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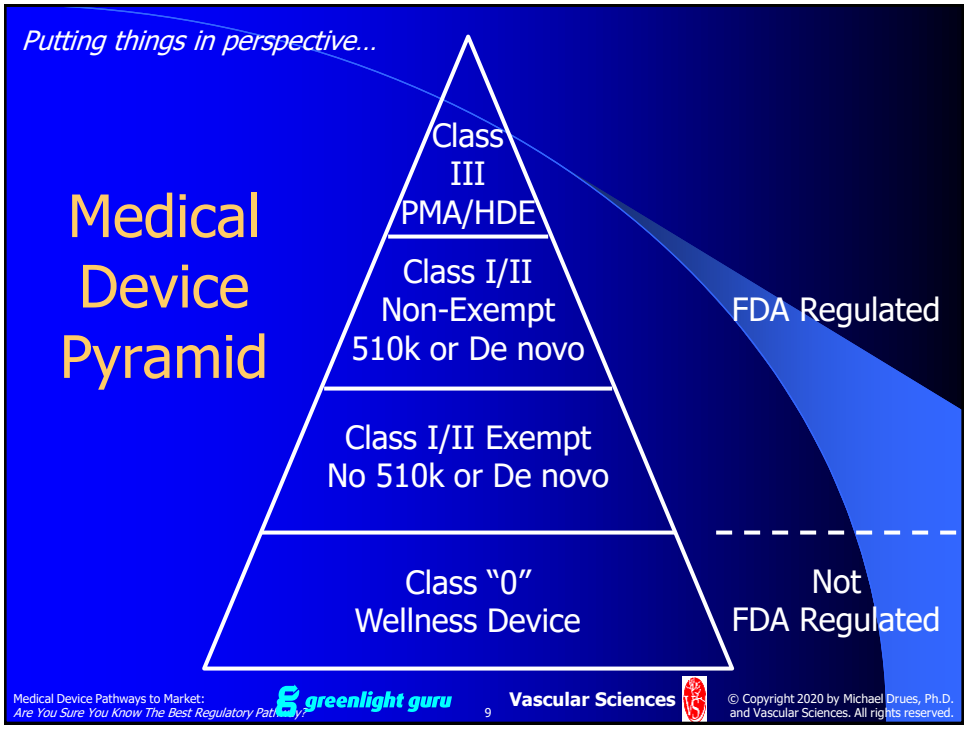
Is this an option for my medical device?



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Breakthrough Device Program:

Is this an option for my medical device?

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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Breakthrough Device Program:

Is this an option for my medical device?

Want More?

www.greenlight.guru/webinar/general-wellness-devices

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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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Breakthrough Device Program:

Is this an option for my medical device?

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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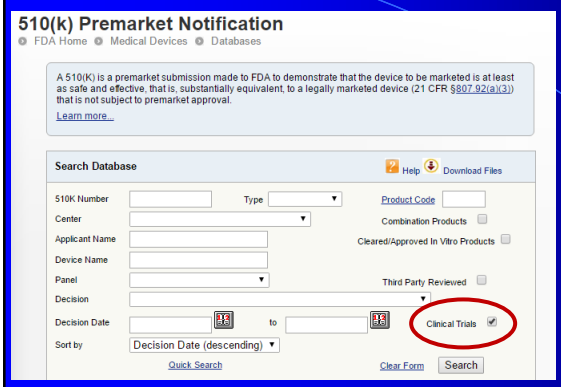
How many 510k devices have clinical data?



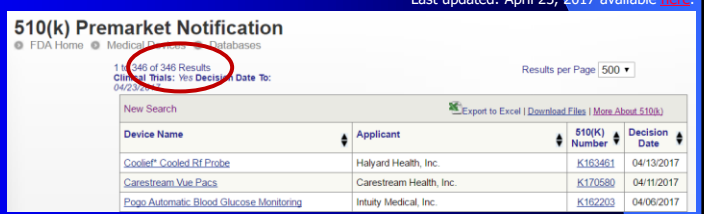
Go to the 510k database…
tick 'Clinical Trials' → 'Search'

Last updated: April 23, 2017 available here.

Result →

Does that seem small?

Is this a problem?



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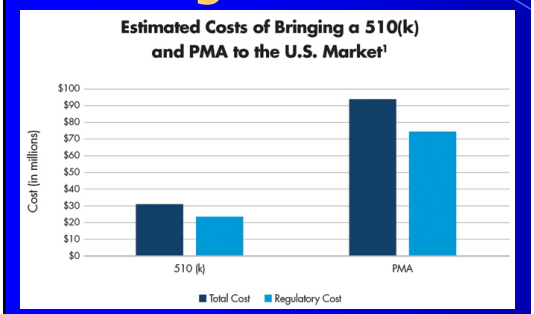
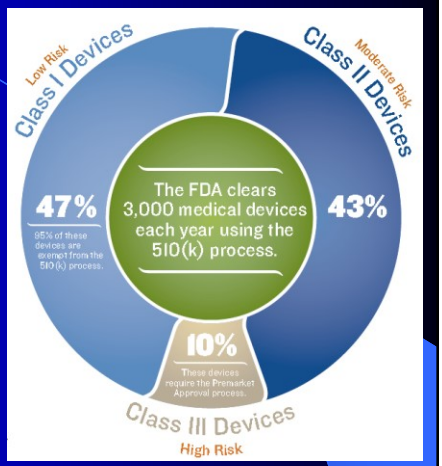
Breakthrough Device Program:

Is this an option for my medical device?

The Costs of Doing Business





Medical Product Outsourcing (Sept., 2017) available here.

510(k) Reform and the Resulting Impact on Medical Device Developers (Novella Clinical, A Quintiles Company, 2013)

Industry reports estimate that it ***costs $31 million on average to bring a 510(k) product to market and $94 million to bring a PMA device to market. Further, more than 75% of those costs are directly related to clearing regulatory requirements.***

Single Sourcing: The Cure for the Common Supply Chain (MDDI Magazine, September 9, 2013)

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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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Breakthrough Device Program:

Is this an option for my medical device?

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

Substantial Equivalence Argument and Risk Mitigation Strategy

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Is there a Governing Equation of the 510k?

Two *fundamental equations* of the 510k are:

1) **510k = SE + Risk**

and

2) **SE = Labeling + Technology**

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

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

Note: Risk = Risk$_{Bucket1}$ + Risk$_{Bucket2}$ + Risk$_{Bucket3}$

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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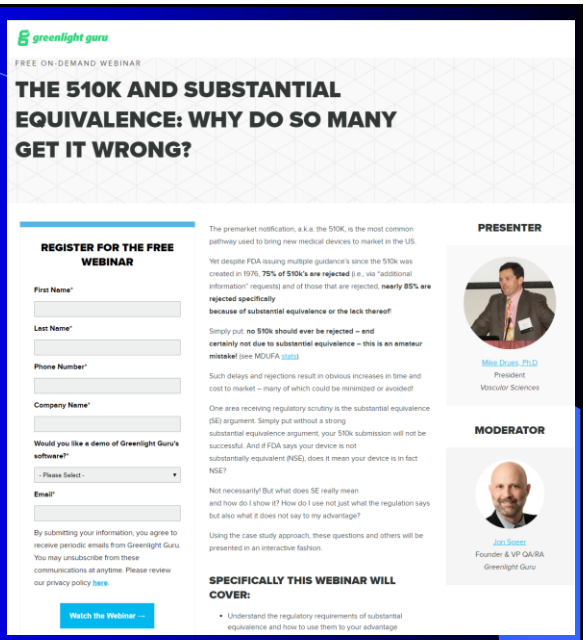
Want more?



www.greenlight.guru/webinar/510k-substantial-equivalence

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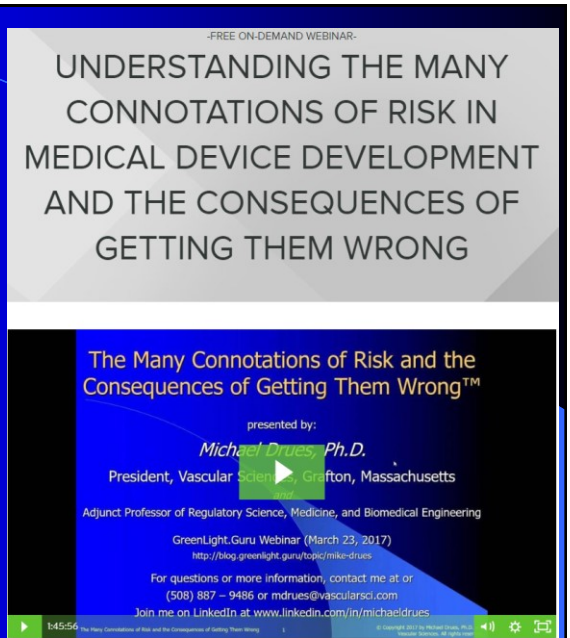
Want more?



www.greenlight.guru/webinar/many-connotations-risk-medical-device-development

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Breakthrough Device Program:

Is this an option for my medical device?

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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Breakthrough Device Program:

Is this an option for my medical device?

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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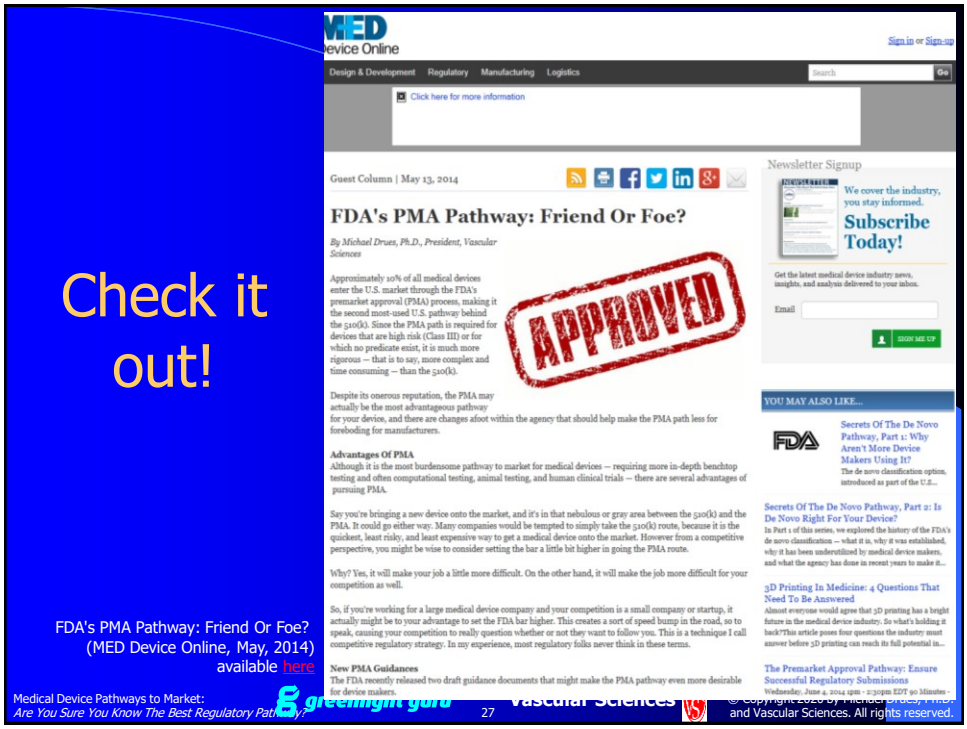

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Breakthrough Device Program:

Is this an option for my medical device?

Want more?

www.greenlight.guru/webinar/pre-market-approval

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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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Breakthrough Device Program:

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 say 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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Breakthrough Device Program:

Is this an option for my medical device?

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

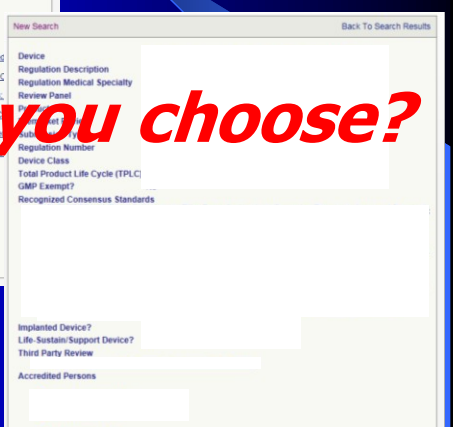
FDA Home ● Medical Devices ● Databases

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	
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Eligible for *Accredited Persons Expansion Pilot Program*
Accredited Persons	Dekra Certification B.v. Regulatory Technology Services, Llc Tuv 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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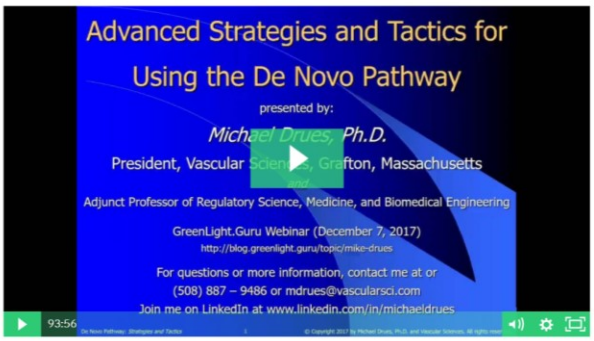
Want more?

FREE ON-DEMAND WEBINAR

ADVANCED STRATEGIES AND TACTICS FOR USING THE DE NOVO PATHWAY



www.greenlight.guru/webinar/de-novo-pathway

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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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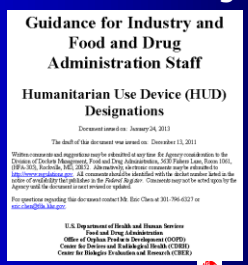
Breakthrough Device Program:

Is this an option for my medical device?

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



Guidance for Industry and Food and Drug Administration Staff

Humanitarian Use Device (HUD) Designations

Document issued on: January 24, 2013

The draft of this document was issued on: December 13, 2011

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding this document contact Mr. Eric Chen at 301-796-6327 or eric.chen@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Orphan Product Development (OOPD)
Center for Devices and Radiological Health (CDRH)
Center for Biologics Evaluation and Research (CBER)

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

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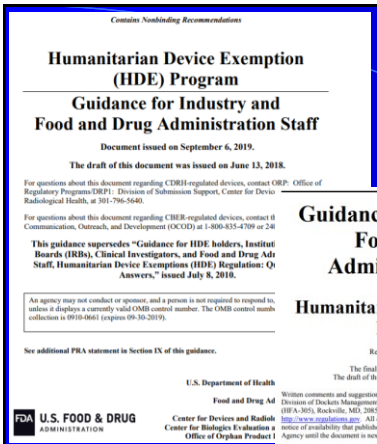
HDE Guidance



Contains Nonbinding Recommendations

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 ORP: Office of Regulatory Programs/DRP1: Division of Submission Support, Center for Devic Radiological Health, at 301-796-5640.

For questions about this document regarding CBER-regulated devices, contact t Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 24

This guidance supersedes "Guidance for HDE holders, Institut Boards (IRBs), Clinical Investigators, and Food and Drug Ad Staff, Humanitarian Device Exemptions (HDE) Regulation: Q 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 numb collection is 0910-0061 (expires 09-30-2019).

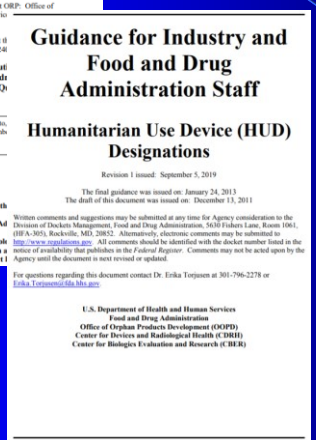
See additional PRA statement in Section IX of this guidance.

U.S. Department of Health

Food and Drug Ad

U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiol
Center for Biologics Evaluation a
Office of Orphan Product



Guidance for Industry and Food and Drug Administration Staff

Humanitarian Use Device (HUD) Designations

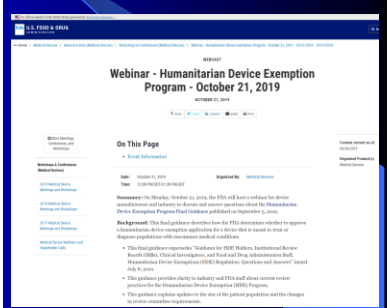
Revision 1 issued: September 5, 2019

The final guidance was issued on: January 24, 2013
The draft of this document was issued on: December 13, 2011

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding this document contact Dr. Erika Torjusen at 301-796-2278 or Erika.Torjusen@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Orphan Products Development (OOPD)
Center for Devices and Radiological Health (CDRH)
Center for Biologics Evaluation and Research (CBER)



Webinar - Humanitarian Device Exemption Program - October 21, 2019

On This Page

- Event Information

Guidance: *Humanitarian Device Exemption (HDE) Program* (Sept, 2019) here
Guidance: *Humanitarian Use Device (HUD) Designations* (Sept, 2019) here
FDA Webinar: *Humanitarian Device Exemption Program* (Oct, 2019) here.
Humanitarian Device Exemptions: FDA Finalizes Guidance (RAPS, Sept 2019) here

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GreenLight.Guru Webinar (April 2, 2020)

www.greenlight.guru/webinar/are-you-sure-you-know-the-best-regulatory-pathway-for-your-new-medical-device

Breakthrough Device Program:

Is this an option for my medical device?

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?

Step One:

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/pdf8/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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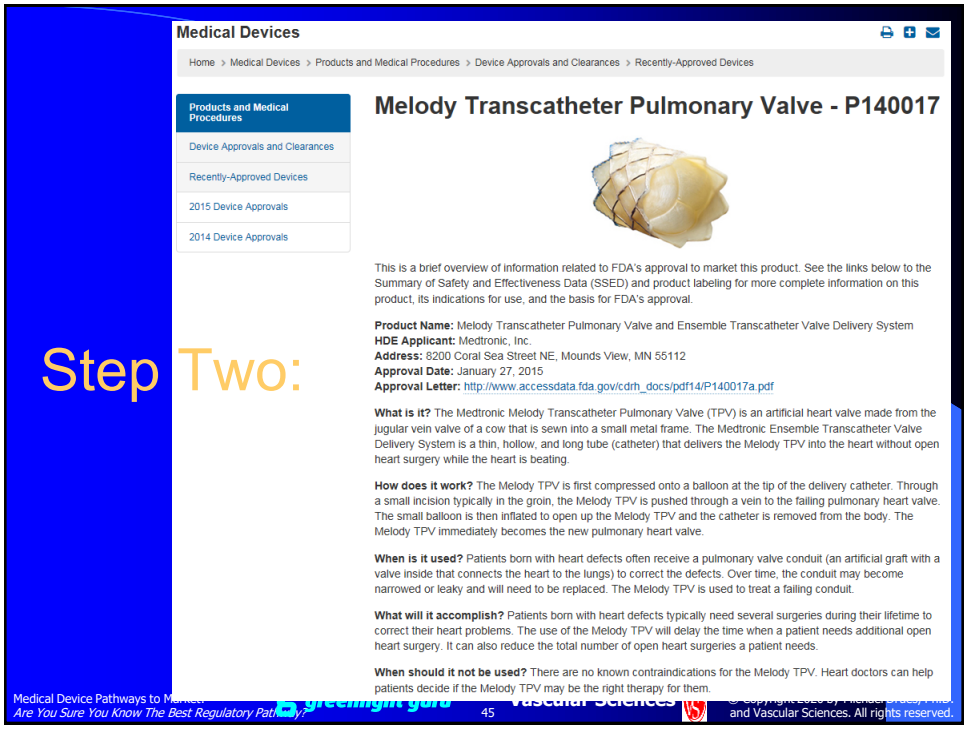
Breakthrough Device Program:

Is this an option for my medical device?



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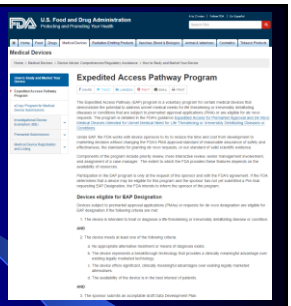
Breakthrough Device Program:

Is this an option for my medical device?

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)
Eligibility	Device that provides for *more effective* treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and meets one of the following criteria: 1. Represents a breakthrough technology, 2. No approved alternatives exist, 3. Offers significant advantages over existing approved alternatives, or 4. The availability of which is in the best interest of the patients.		
Applications Accepted	PMA, DeNovo, 510(k), PDP	IDE, PMA, DeNovo[1]	Q-Sub, IDE, PMA, DeNovo, 510(k)[2]
Interactive Review	No	Yes	Yes
Sr. Management Involvement	No	Yes	Yes
Sprint Discussions	No	No	Yes
Data Development Plan(DRD)	No	Yes	Not mandated
Clinical Protocol Agreement	No	No	Yes
Regular Status Updates	No	No	Yes
When to submit request for designation	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
FDA timeframe for granting/rejecting request	• 510(k) or DeNovo = 14 days within receipt of submission • PMA: during the 45 days filing review	Within 30 days of receipt[3]	Within 60 days of receipt
Review TIme	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

[1] Not all provisions of the EAP are applicable to DeNovo applications.
[2] Includes combination products under the device pathway.
[3] 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

Breaking Through FDA's New "Accelerated" Pathway (MDDI, May 29, 2018) here.

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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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Breakthrough Device Program:

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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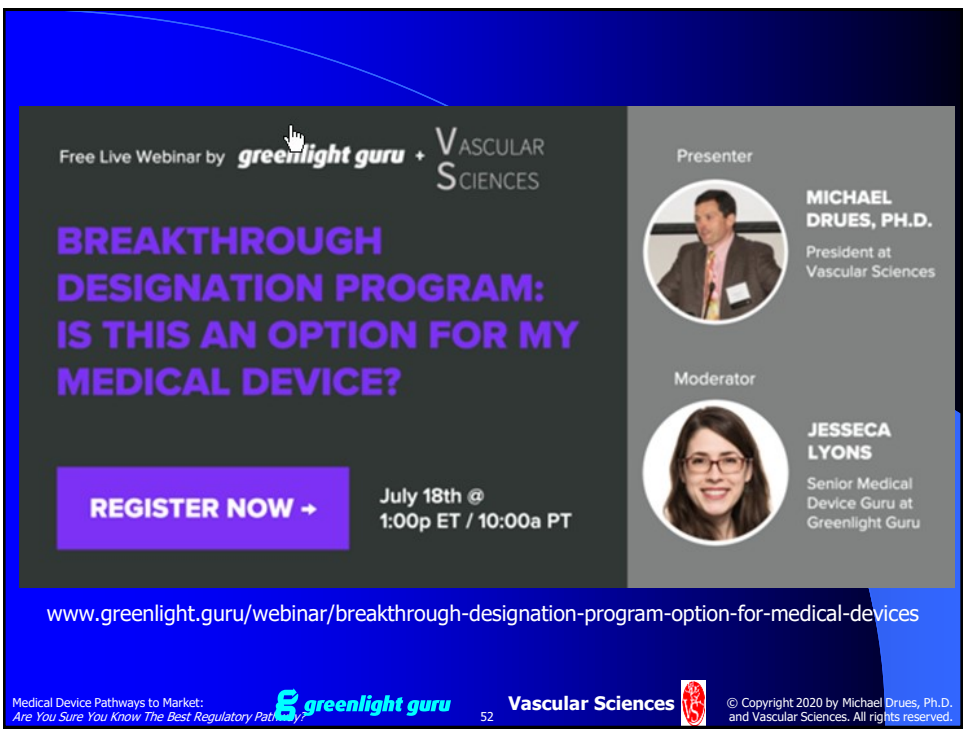

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Breakthrough Device Program:

Is this an option for my medical device?

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

Safer Technologies Program for Medical Devices (STeP)

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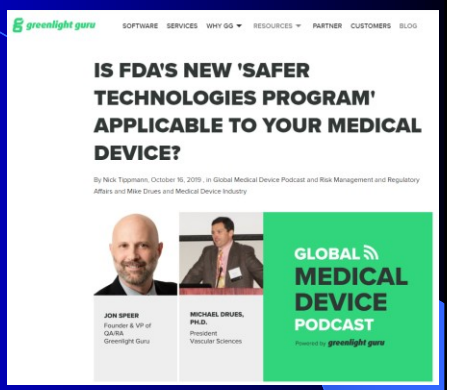
More about STeP

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



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

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Breakthrough Device Program:

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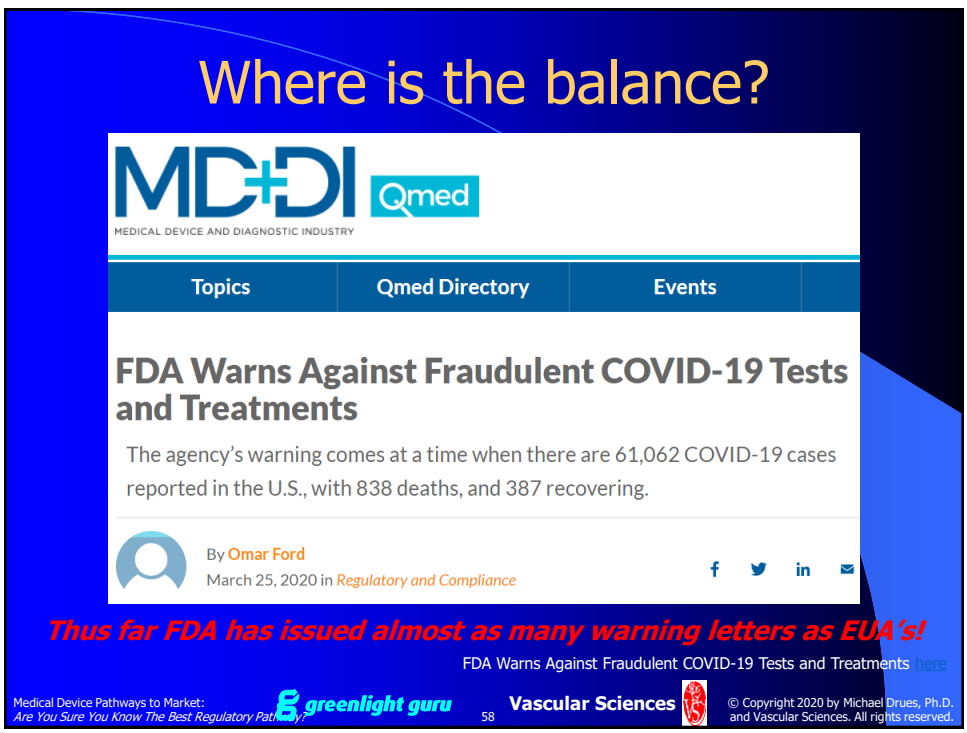

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Breakthrough Device Program:

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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)

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

This is just the beginning!

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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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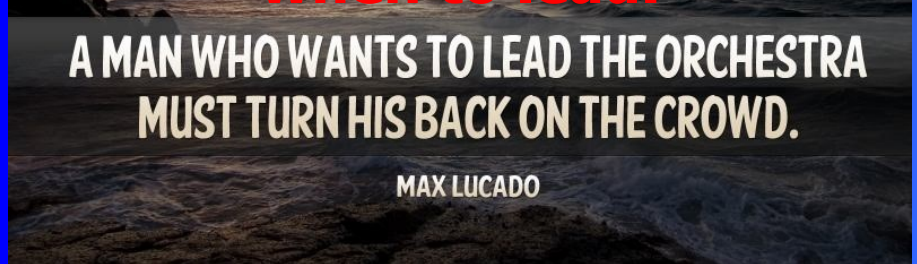
There are many regulatory consultants out there…

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!



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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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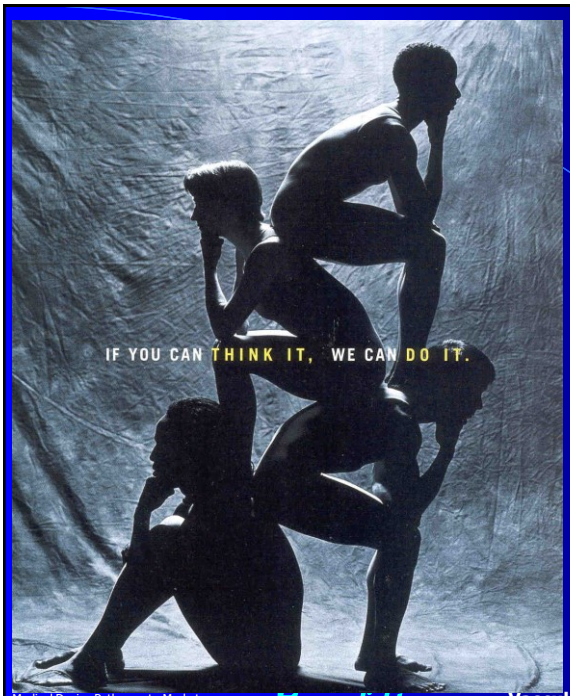
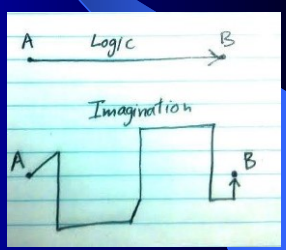


"Imagination is more important than knowledge, for while knowledge points to all there is, imagination points to all that can be."

Albert Einstein



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

Albert Einstein

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