

Special Controls:

What are they and how can we use them to our advantage?

presented by:

Michael Drues, Ph.D.

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and

Adjunct Professor of Regulatory Science, Medicine
and Biomedical Engineering

Cornell University Graduate Dept. of Biomedical Engineering

GreenLight.Guru (May 19, 2022)

www.greenlight.guru/webinar/advantages-of-special-controls

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Speaker Biography



Michael Drues, Ph.D., is President of Vascular Sciences, an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including stimulating & innovative educational programming, creative regulatory strategy & complete regulatory intelligence, regulatory submission design, FDA presentation preparation & defense, brain-storming sessions, prototype design, product development, benchtop & animal testing, , clinical trial design,

reimbursement, clinical acceptance, business development & technology assessment.

Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University in Ames, Iowa. He has worked for and consulted 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 (FDA), Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services (CMS) 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 U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the US Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world.

Finally, as an Adjunct Professor of Regulatory Science, Medicine, Biomedical Engineering & Biotechnology, Dr. Drues teaches graduate courses in Regulatory Affairs & Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs & Product Development, Combination Products, Pathophysiology, Medical Technology & Biotechnology at several universities & medical schools on-ground & on-line.

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](#) or LinkedIn [here](#).

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Introductions



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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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Is it possible to think regulatory?

"Science is a way of thinking much more than it is a body of knowledge."
Carl Sagan (1934–1996)
American astronomer, author and science journalist

So how about this?

"Regulatory affairs is a way of thinking much more than it is a body of rules and regulations – or at least it should be!"
Michael Drues (1964–)
Regulatory Strategist and Amateur Philosopher ©
www.meddeviceonline.com/author/michael-drues

Maybe Carl Sagan would be proud!

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

- ✓ What are special controls? When and how are they used?
- ✓ Why do we call them "special" controls? Are they really "special?"
- ✓ General vs. special controls: When and why do we need both?
- ✓ Does your device require special controls? How can you find out?
- ✓ For class II exempt devices, do special controls still apply?
- ✓ How do special controls vary in a 510k vs. in a de novo?
- ✓ Virtually all special controls ensure safety... what about efficacy?
- ✓ Existing standard for a special control vs. creating a new standard?
- ✓ Lots more tips and tricks... time permitting!
- ✓ Final thoughts...

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Special Controls:

What are they and how can we use them to our advantage?

What are special controls
When and how are they used
Why call them "special" controls
Are they really special



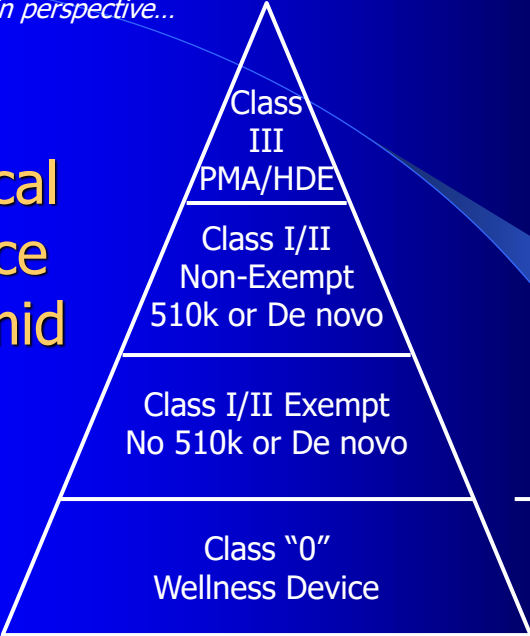
Note:
Most people have a myopic view of "special" controls... including FDA!

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Putting things in perspective...

Medical Device Pyramid



Class	Regulation
Class III PMA/HDE	FDA Regulated
Class I/II Non-Exempt 510k or De novo	FDA Regulated
Class I/II Exempt No 510k or De novo	Not FDA Regulated
Class "0" Wellness Device	Not FDA Regulated

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A risk based approach for medical devices since 1976

True is theory... Increasing Risk →
 Classification determines extent of regulatory control (Risk Based)

Class I	Class II	Class III
<ul style="list-style-type: none"> •General Controls 	<ul style="list-style-type: none"> •General controls •Special controls <p><i>Specific Controls</i></p>	<ul style="list-style-type: none"> •General controls •Premarket approval (PMA) <p><i>More Specific Controls</i></p>
<p>General Controls</p> <ul style="list-style-type: none"> •Electronic Establishment Registration •Electronic Device Listing •Quality Systems •Labeling •Medical Device Reporting (MDR) •Pre-market notification (510(k) for less complex) 		<p>Special Controls (addressing Risk)</p> <ul style="list-style-type: none"> •Guidelines (e.g., Glove Manual) •Mandatory Performance Standard •Recommendations or Other Actions •Special Labeling (e.g. 882-5970 Crania Orthosis)

Reality is far more complex!

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Presenter

MICHAEL DRUES, PH.D.
President at Vascular Sciences

Moderator

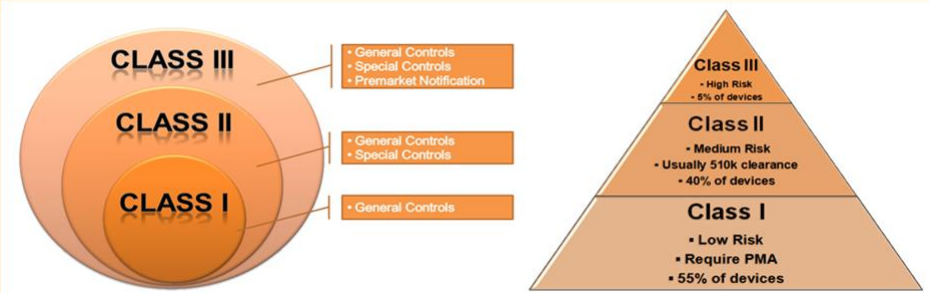
JON SPEER
Founder & VP of QA/RA at Greenlight Guru

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US Classification



CLASS III

- General Controls
- Special Controls
- Premarket Notification

CLASS II

- General Controls
- Special Controls

CLASS I

- General Controls

Class III

- High Risk
- 5% of devices

Class II



- Medium Risk
- Usually 510k clearance
- 40% of devices

Class I

- Low Risk
- Require PMA
- 55% of devices

Center for Emerging Neurotechnologies, University of Cincinnati

Can you find the errors?
Hint: There are at least 3!

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Special Controls:

What are they and how can we use them to our advantage?

General vs. special controls:
When and why do we need both




In a nutshell, three types of Regulatory Controls:
General Controls are general... apply to everything (or do they?)
Special Controls are uhh... special? how about specific?
[note: 126 Special Controls [here](#).]




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Does your device require special controls
How can you find out



Short answer:
Its your job to do your homework not FDA's!
Where to look? Here's a start...

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Where to look?

If you're working on a me-too:

- ✓ CDRH product code database [here](#)
Ex: PTCA Catheter [DOY](#)
- ✓ Predicate (if applicable)
Ex: PTA Catheter 510k summary ([K201377](#))

If you're working on anything:

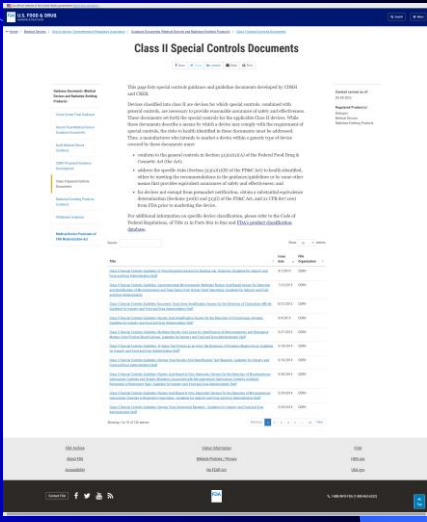
- ✓ Guidance document database [here](#)
- ✓ Rec Consensus Standards database [here](#)
- ✓ CDRH List of 126 Special Controls [here](#)
Ex: Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters - Class II Special Controls [here](#)



If you're working on something new/novel:

Create your own!

Just a start... think outside the FDA box!

For your device, you should know MORE than anyone else... including FDA!



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Do you want to imitate or innovate?



When people are free to do as they please, they usually imitate each other.

Eric Hoffer (1902–1983) was an American social writer and philosopher. He produced ten books and was awarded the Presidential Medal of Freedom in 1983.

If you think adventure is dangerous, try routine – it's lethal!

Paulo Coelho (1947-), Brazilian lyricist and novelist, author of *The Alchemist*



Remember, we must always be willing to... **Think different.**

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Special Controls:

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For class II exempt devices, do special controls still apply?



Short answer: *Maybe!*

Let's look at an example...

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Case Study: Refrigerator

Is a refrigerator a medical device?
Could it depend on what you put in it?



Could you store blood in your refrigerator at home?
Absolutely... but that would be off-label use!

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New Search Back to Search Results

Device	Refrigerator, Freezer, Blood Storage
Regulation Description	Blood storage refrigerator and blood storage freezer.
Regulation Medical Specialty	Hematology
Review Panel	Hematology
Product Code	KSE
Premarket Review	Center for Biologics Evaluation & Research (CBER)
Submission Type	510(K) Exempt
Regulation Number	864.9700
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

Note: Class II devices the Food and Drug Administration (FDA) has also published a [list of class II \(special controls\) devices](#) subject to certain limitations, that are exempt from premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (FDAMA) and the 21st Century Cures Act of 2016 (Cures Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet requirements of FDAMA and the Cures Act.


Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2019]
[CITE: 21CFR864.9700]

 See Related Information

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



PART 864 -- HEMATOLOGY AND PATHOLOGY DEVICES
Subpart J--Products Used In Establishments That Manufacture Blood and Blood Products

Sec. 864.9700 Blood storage refrigerator and blood storage freezer.

(a) *Identification.* A blood storage refrigerator and a blood storage freezer are devices intended for medical purposes that are used to preserve blood and blood products by storing them at cold or freezing temperatures.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 864.9.

[45 FR 60650, Sept. 12, 1980, as amended at 63 FR 59226, Nov. 3, 1998]

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Why class II?
Why 510k exempt?
Why 39 510k's if 510k exempt?

39 [KSE 510k's here](#) (1980-1999)

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How do special controls vary in a 510k vs. de novo?

Short answer:
Special controls are one of the biggest competitive advantages of the de novo!

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Using Regulation as a Competitive Advantage

"A key tactical decision faced in the de novo process is whether to recommend the class for the device (remember, this is optional). It is recommended that a manufacturer suggest the class that gives it most control over its destiny. For a Class II device, this includes trying to influence the type of controls that might be required, especially something that might be difficult for competitors to match."

Or put another way, think...

Competitive regulatory strategy!

"The "de Novo" 510(k) Process and the Reclassification of Class III Devices" (RAPS, March, 2006)

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The "de Novo" 510(k) Process and the Reclassification of Class III Devices

By Michael A. Selt, Esq.

For medical device makers today, a major challenge of the Device Amendments of 1976 is resolving the conflict between the need to be innovative—an essential for patient protection—and the fact that, if they are, their device may automatically fall into Class III and require premarket approval rather than being marketed via the "substantially equivalent" route of the 510k submission. This article discusses this tension and a mechanism the law now provides for device makers to resolve the conflict and avoid the more onerous premarket approval process.

Default Class III Status: How It Happens and Its Implications

Under the original '76 Amendments, if a device involves a new technology that is not substantially equivalent to either a pre-'76 device not requiring a premarket approval application (PMA) or a post-'76 device FDA already has classified into Class II or I, then that "new" device is automatically placed into Class III, requires a PMA. Now, almost 50 years since 28 May 1976—the Device Amendments enactment date—logically, it is increasingly harder to claim that a really "new" device is substantially equivalent to many devices eligible for 510k submission.

For FDA, automatic Class III status for new devices clearly protects the public health because any ostensibly new technology winds up in the most protective device regulatory regime. Functionally, because it is "automatic," FDA's administrative burden is minimized because it is not required to distinguish between those devices placed in Class III because their risk profiles truly warrant that level of regulation and those products that, due to the fact that it is now decades since the '76 Amendments, placed there III because, temporarily, they have only just been developed.

While automatic Class III status may be easier for FDA, the automatic Class III status of the '76 Amendments, meant to handle new technology, created challenges for industry. This, by pigeonholing some devices into Class III where they—while chronologically new or novel in the United States—did not warrant the expense or time of a PMA because they more closely matched the risk profiles of Class II or even Class I devices. Automatic Class III status was overkill, critics argued, as it mandated proof of substantial evidence of safety and effectiveness via clinical studies to support PMAs for devices that may not have been that risky. Not only was a PMA an unnecessary regulatory burden, it also raised the ethical question of needlessly exposing human subjects to clinical investigations.

To help resolve the challenge of automatic Class III status, the de novo petition process emerged as part of FDA reform efforts, culminating in the 2007 Food and Drug Administration Modernization Act (FDAMA). FDAMA's device provisions reflected, in part, internal changes by FDA's Center for Devices and Radiological Health (CDRH) during the mid-'90s—dubbed "re-engineering" by the center—that focused on having regulatory decisions to risk. That risk approach is, essentially, what Congress adopted in FDAMA's device provisions, particularly the de novo 510k process.

FDAMA and Automatic Class III Status

Section 207 of FDAMA created a new statutory mechanism for getting out of automatic Class III status by allowing a petition to FDA to move the "new" device to Class II or I status, as though it had always been so classified; hence, either "out" or "from" the new FDA's key task in approving or denying a de novo petition under FDAMA is not to decide whether a device is new technology, but to examine the risks it presents and whether those risks can be handled via Class II special controls or Class I general controls.

In talking about risk and the de novo process, however, FDAMA did not provide guidance on the risk levels that allow a product to escape Class III status. In its February 1998 guidance on the de novo process,³ FDA stated that the de novo process is for "lower risk" devices. Thus, it appears FDA would not favor reclassification of devices posing arguably "higher" risks, whose risk can be controlled via Class II special controls or Class I general structures.⁴

The Logistics of the de Novo Petition Process

To use the de novo process, a manufacturer must first:



34 March 2006

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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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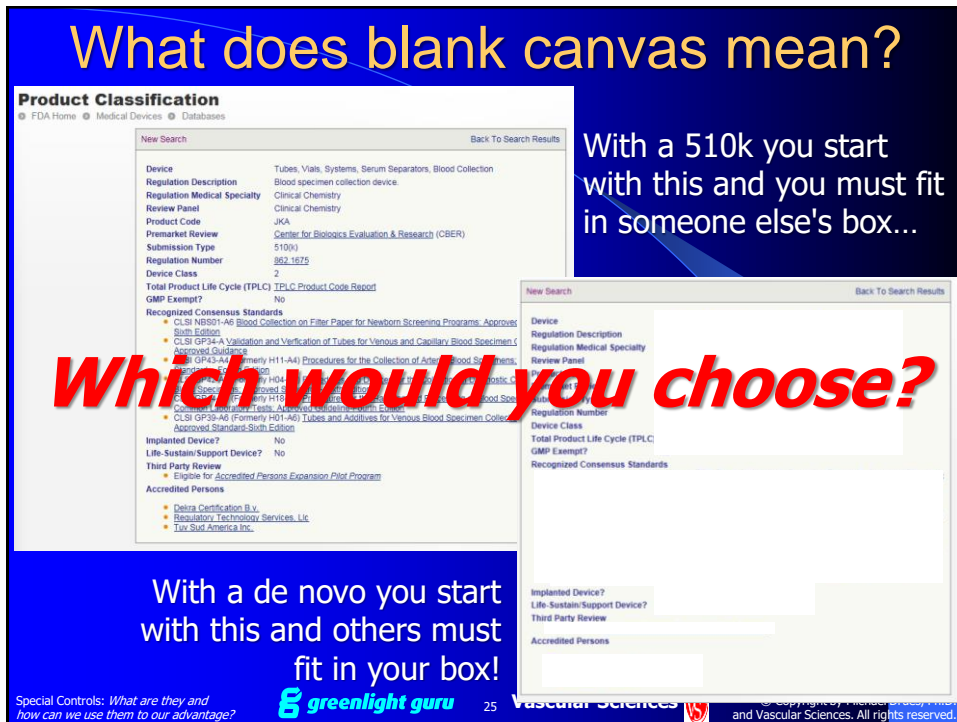
What does blank canvas mean?

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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President, Vascular Sciences, Grafton, Massachusetts

Adjunct Professor of Regulatory Science, Medicine, and Biomedical Engineering

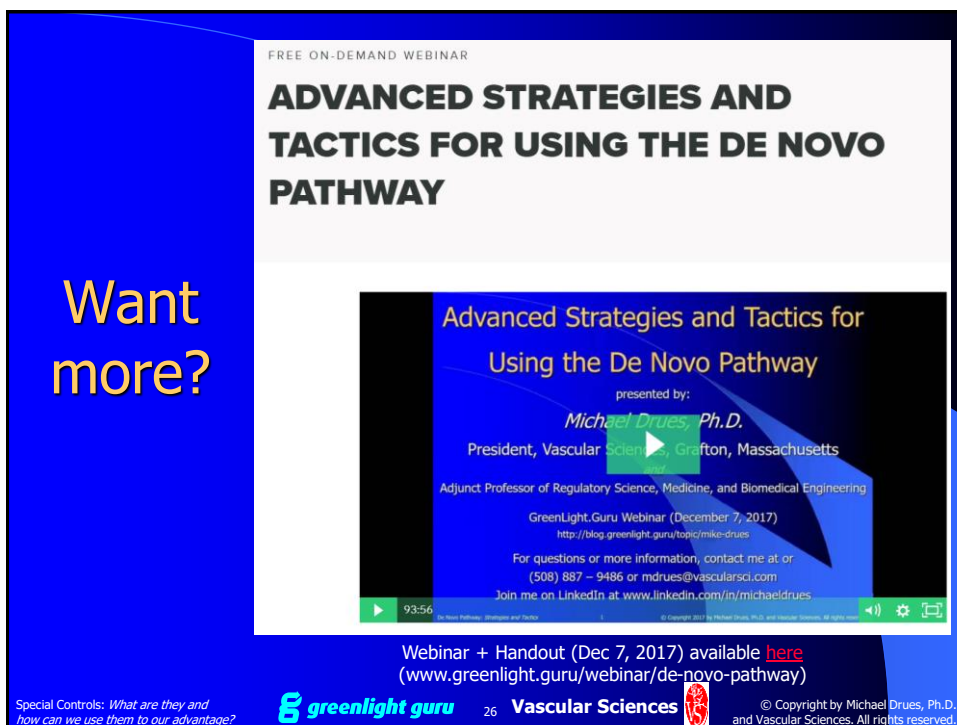
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The de novo
pathway -
Strategies and
Tactics to Use
and Avoid**

<http://www.globalregulatorypress.com/>

Abstract available [here](#).

The De Novo Pathway (J Med Dev Reg, May, 2015)

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MAY 2015 VOLUME 12 (2)

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- Guest Editorial: The de novo pathway - strategies and tactics to use and avoid
- Guest Editorial: Are the costs associated with the application of basic and general standards proportionate to the risk of a medical device?
- 21st Century Ques A&I discussion draft: key positions relating to medical devices
- Directive 93A2/EEC examples of inadequately defined or undefined terms and proposed interpretations
- News updates from Europe, North America, Central & South America, Asia, Africa & the Middle East and global interest
- Country overview: Indonesia

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Virtually all special controls are intended to ensure safety... what about efficacy




Reminder:
There is NO 510k requirement for safety and efficacy!

Better question:
Can a clinical trial be "required" as a special control?

Answer:
Yes... if you "spin" it properly! How?

Special Controls: *What are they and how can we use them to our advantage?*



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<https://www.greenlight.guru/webinar/advantages-of-special-controls>




Special Controls:

What are they and how can we use them to our advantage?

Existing standard for a special control vs. creating a new standard




MOST powerful and LEAST commonly used strategy for special controls!
How about an example...

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Case Study: Sonablate

HIFU with the Sonablate® 500



The Sonablate® 500 is a medical device that uses HIFU to thermally ablate the prostate.

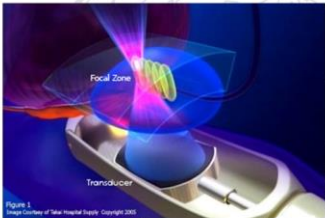





Figure 1. Reproduced with permission of Sona Health Supply. Copyright 2005

Updated 12/7/07

All based on publicly available information... but you will have to dig deep to find it!
Note: complete 6446 page (redacted) de novo submission can be obtained via FOI request [here](#).
Sonablate HIFU Animation [here](#) (YouTube) (2 min) / Basic HIFU Video [here](#) (YouTube) (1 min)

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Special Controls:

What are they and how can we use them to our advantage?

Case Study: Sonablate

Device Classification Name High Intensity Ultrasound System For Prostate Tissue Ablation

De Novo Number DEN150011

Device Name Sonablate 450

Requester Sonacare Medical, LLC, 801 E. Morehead St, Suite 201, Charlotte, NC 28202

Contact Dawn Byrd Burleson

Regulation Number 876.4340

Classification Product Code PLP

Date Received 03/23/2015

Decision Date 10/09/2015

Decision Granted (DENG)

Classification Advisory Committee Gastroenterology/Urology

Review Advisory Committee Gastroenterology/Urology

Reclassification Order [Reclassification Order](#)

FDA Review [Decision Summary](#)

Type Direct

Device High Intensity Ultrasound System For Prostate Tissue Ablation

Definition Prostate tissue ablation

Physical State The system consists of a console, a probe with therapy transducer(s), and single use accessories.

Technical Method Uses high intensity ultrasound to heat target tissue within the prostate gland, causing coagulation necrosis of that tissue.

Target Area The prostate gland

Regulation Medical Specialty Gastroenterology/Urology

Review Panel Gastroenterology/Urology

Product Code PLP

Premarket Review Reproductive, Gynecology and Urology Devices (DHT3B) Reproductive, Gynecology and Urology Devices (DHT3B)

Submission Type 510(k)

Regulation Number 876.4340

Device Class 2

Total Product Life Cycle (TPLC) [TPLC Product Code Report](#)

GMP Exempt? No

Summary Malfunction Reporting Eligible



Implanted Device? No

Life-Sustain/Support Device? No

Third Party Review Not Third Party Eligible

Points to Consider:

- ✓ Class II medical device brought to market via de novo ([DEN150011](#))
- ✓ New product code created: [PLP](#)
- ✓ New regulation created based on de novo (incl. variety of special controls) is: [876.4340...](#)

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Power of De Novo and Special Controls

Note: in some cases, special controls are listed in the Product Code description. In this example, they are listed in the Code of Federal Regulations description ([876.4340](#)).

Always important to check both!

Notes from Redacted Submission:

- Summary of "proposed" special controls pp. 67-68
- Details of "proposed" special controls p.69+
- Note difference(s) in "proposed" special controls i.e., those proposed in the original de novo submission and the actual special controls listed in [876.4340](#)**
- In other words, you can always ask but you don't always get... but in this case, the Company got the important ones.

You have to pick your battles! ☹️

Part 876 -- GASTROENTEROLOGY-UROLOGY DEVICES

Subpart E -- Surgical Devices

Sec. 876.4340 High intensity ultrasound system for prostate tissue ablation.

(a) Identification. A high intensity ultrasound system for prostate tissue ablation is a prescription device that transmits high intensity therapeutic ultrasound energy into the prostate to thermally ablate a defined, targeted volume of tissue, performed under imaging guidance. This classification does not include devices that are intended for the treatment of any specific prostate disease and does not include devices that are intended to ablate non-prostatic tissues/organs.

(b) Performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(1) Characterization of acoustic pressure and power output at clinically relevant levels

(11) Measurement of targeting accuracy and reproducibility of high intensity ultrasound output.

(111) Ultrasonographic beam verification testing at target and non-target tissues;

(1v) Electrodosimetry

(v) Electrodosimetry

(2) Software verification testing and

(3) The elements of the device that may contact the patient's mucosal tissue must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components that contact the patient's mucosal tissue.

(5) Performance data must demonstrate the sterility of the device components that contact the patient's mucosal tissue.

(6) Performance data must support the instructions for reprocessing all reusable components.

(7) In vivo testing must demonstrate that the device thermally ablates targeted tissue in a controlled manner without damage to adjacent tissues.

(8) Clinical testing must demonstrate the evidence of prostatic ablation, and demonstrate that the device performs as intended under anticipated conditions of use.

(9) Training must be provided so that upon completion of the training program, the physician can:

(i) Use all the key features of the device;

(ii) Accurately identify the target region of the prostate; and

(iii) Perform the ablation procedure on the target tissue.



(10) Labeling must include:

(i) A section that summarizes the clinical testing results, including the adverse event profile and evidence of prostate ablation achieved; and

(ii) An expiration date or shelf life for single use components.

(12 FR 49727, Oct. 2, 2017)

This is the end result... not the beginning!

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Special Controls:

What are they and how can we use them to our advantage?

With Power Comes Responsibility



The interaction between patents and FDA's De Novo and 510(k) regulatory pathways has the potential to threaten follow-on innovation for medical devices.



The US Food and Drug Administration (FDA) has long been criticized — perhaps unfairly — for failing to expeditiously approve groundbreaking

Those controls related to the heat degradation properties of such bandages; unexpectedly, heat from the skin degraded one component of the gel into formaldehyde. Because De

potentially anticompetitive patent strategy. De Novo applicants may patent the core technological characteristics of their devices, essential for FDA's determination that


De Novo applicants may patent the core technological characteristics of their devices, essential for FDA's determination that the follow-on application is "substantially equivalent." In addition, the De Novo applicant can advocate before the agency that its "performance standards" are, in fact, core technological characteristics for the device's "special controls." As a result, a follow-on applicant is given a fatal choice: it must either admit that it uses the same technological characteristics as the patented, predicate device — essentially, an admission of patent infringement — or that it uses different technological characteristics, which is an admission that the device is not substantially equivalent to the predicate. In short: **patenting core technological characteristics of a De Novo device and tying performance standards to these underlying technological characteristics gives follow-on developers an impossible path toward entry.**

Nature Biotechnology (Sept, 2020) [here](#).

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If Time Permits...



BONUS QUESTIONS

AND ANSWERS BELOW

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Special Controls:

What are they and how can we use them to our advantage?

Can special controls be added to existing 510k or product code



Short answer:

Yes but not common!

And what if...

a special control is added to your product code?

Here's a real example...

Special Controls: *What are they and how can we use them to our advantage?*



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Case Study:
Topical Tissue
Adhesives a.k.a.
Liquid Band-Aids



"...special controls for De Novo devices present a problem to FDA because **the requirements to ensure "safety and effectiveness" are difficult to know without extensive testing in the field.** In one case, *topical tissue adhesives* — 'liquid bandages' — **were found to need special controls a full decade after they were first introduced.** Those controls related to the heat degradation properties of such bandages; unexpectedly, heat from the skin degraded one component of the gel into formaldehyde. **Because De Novo devices are,** as the name suggests, **new device types, problems such as these present the quandary of how to ascertain,** with minimal historical comparisons, **which special controls would be needed to ensure their safety and effectiveness."**

Nature Biotechnology (Sept, 2020) [here](#).

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Special Controls:

What are they and how can we use them to our advantage?

Similar question:

Can a new 510k create a new product code

Remember...



"When you hear hoofbeats, think of horses not zebras".
Prof Theodore Woodward, circa 1948



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Rules and Exceptions

*Average regulatory professionals know the rules...
better regulatory professionals know the exceptions...
the best regulatory professionals know the exceptions to the exceptions!*



There is no exception to the rule that every rule has an exception.
James Thurber

James Thurber (1894 – 1961) was an American cartoonist, author, journalist and playwright known for his cartoons and short stories, published in The New Yorker magazine.

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Special Controls:




What are they and how can we use them to our advantage?

When to propose special control(s)



Choices:
During pre-sub? In submission? Another time?

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What's the special controls litmus test?

Why do we need special controls
What happens if we don't have them



Applies to manufacturers AND FDA!
...or at least it should! ☺

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Special Controls:

What are they and how can we use them to our advantage?

THE FINAL QUESTION




What are "acceptable" special controls but maybe shouldn't be



Regrettably...




There are many!

FDA...



Are you listening?


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What's the



Follow special controls because they are necessary...
not because they are required.

Reminder: *the surgery went perfectly but the patient died anyway!*




Create special controls when necessary...
and do so to your competitive advantage!

Reminder: *think competitive regulatory strategy!*

But

Do so responsibly!

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Special Controls:

What are they and how can we use them to our advantage?



 **Here's what just talked about...**

- ✓ What are special controls? When and how are they used?
- ✓ Why do we call them "special" controls? Are they really "special?"
- ✓ General vs. special controls: When and why do we need both?
- ✓ Does your device require special controls? How can you find out?
- ✓ For class II exempt devices, do special controls still apply?
- ✓ How do special controls vary in a 510k vs. in a de novo?
- ✓ Virtually all special controls ensure safety... what about efficacy?
- ✓ Existing standard for a special control vs. creating a new standard?
- ✓ Lots more tips and tricks... time permitting!
- ✓ Final thoughts...

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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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Special Controls:




What are they and how can we use them to our advantage?

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

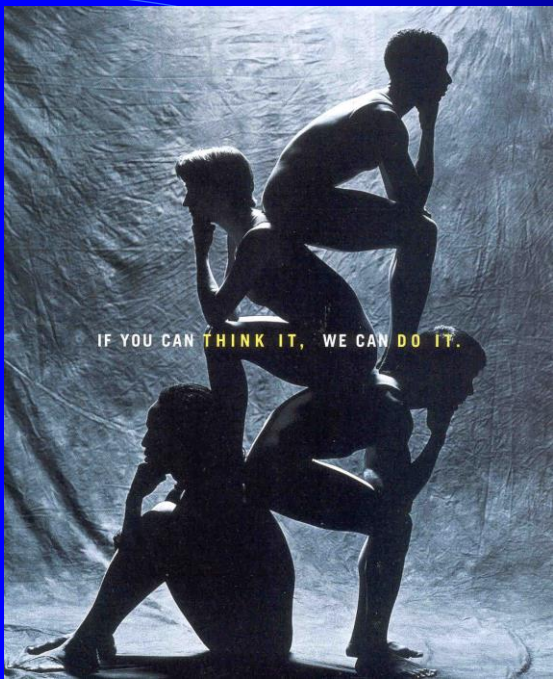


Rules are mostly made to be broken and are too often for the lazy to hide behind.

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.

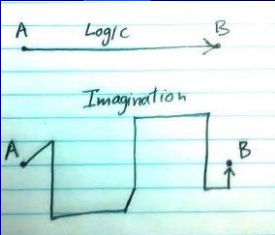
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“Imagination is more important than knowledge, for while knowledge points to all there is, imagination points to all that can be.”

Albert Einstein



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

Albert Einstein

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Special Controls:

What are they and how can we use them to our advantage?

Taking inspiration from one of best...




"Here's to the crazy ones. The misfits. The rebels. The troublemakers. The round pegs in the square holes. The ones who see things differently. They're not fond of rules. And they have no respect for the status quo. You can quote them, disagree with them, glorify or vilify them. About the only thing you can't do is ignore them. Because they change things. They push the human race forward. And while some may see them as the crazy ones, we see genius. Because the people who are crazy enough to think they can change the world, are the ones who do."



Steve Jobs (1955 – 2011), entrepreneur, marketer and inventor, the co-founder of Apple Inc. and widely recognized as a pioneer of the personal computer revolution.

More importantly...

"Imagine where we could be if discontent for the status quo was the norm rather than the exception."

Can you guess who said this?



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Questions?

Comments?

Suggestions?

Criticisms?

Complaints?

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