Special Controls:

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

presented by:

Michael Drues, Ph.D.

President, Vascular Sciences
Carlsbad, California

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

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

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 programing, creative regulatory strategy & completive 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 Medicare 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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For questions or more information, contact me at or

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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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Special Controls:

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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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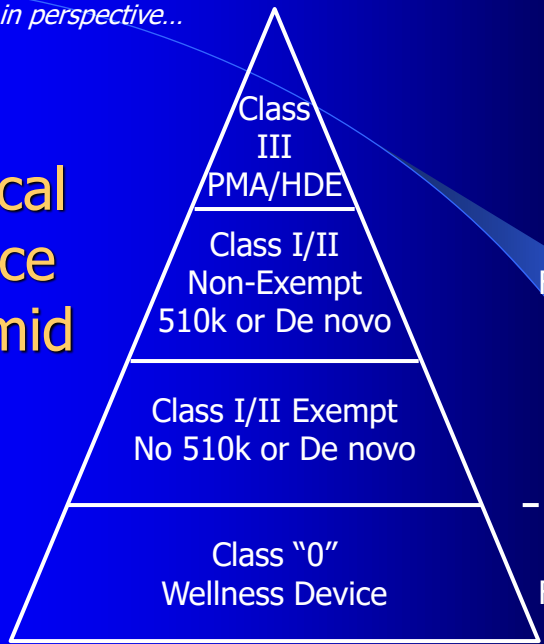
Putting things in perspective…

Medical Device Pyramid



FDA Regulated

Not FDA Regulated

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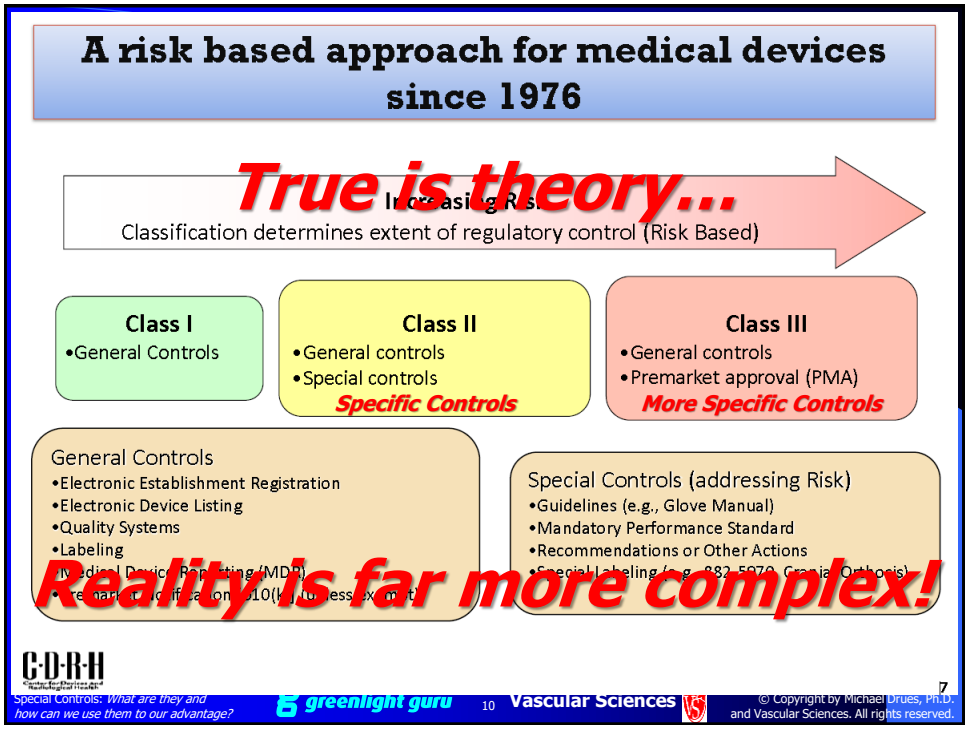

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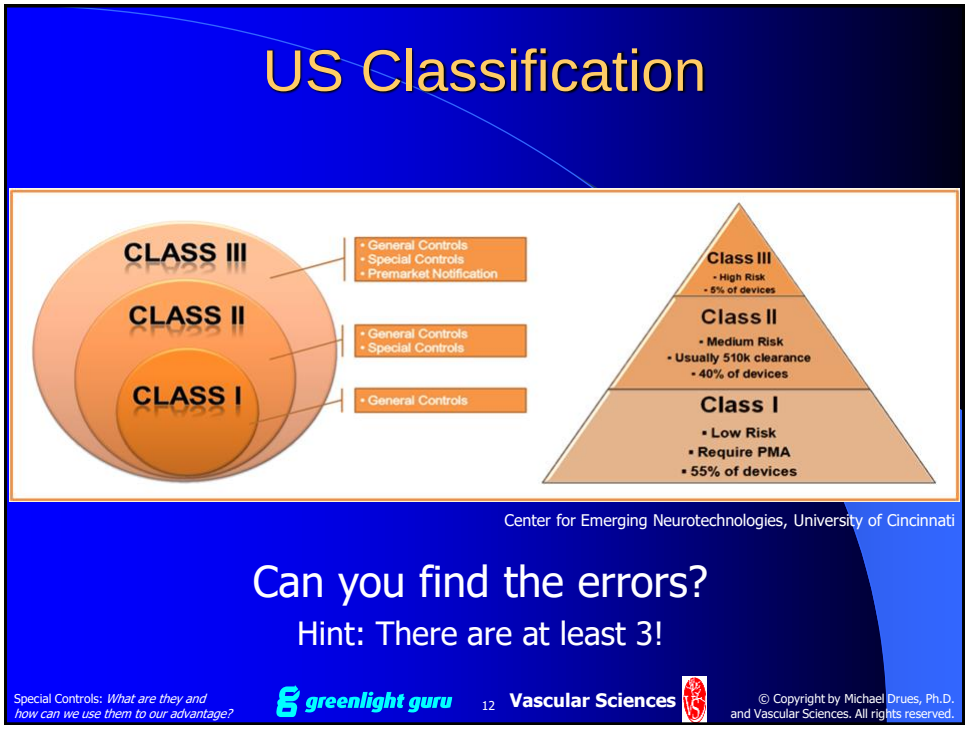

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Special Controls:

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.]

Special Controls: *What are they and how can we use them to our advantage?* greenlight guru 13 Vascular Sciences

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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 DQY
- ✓ Predicate (if applicable)
  - Ex: PTA Catheter 510k summary (K201377)

If you're working on anything:

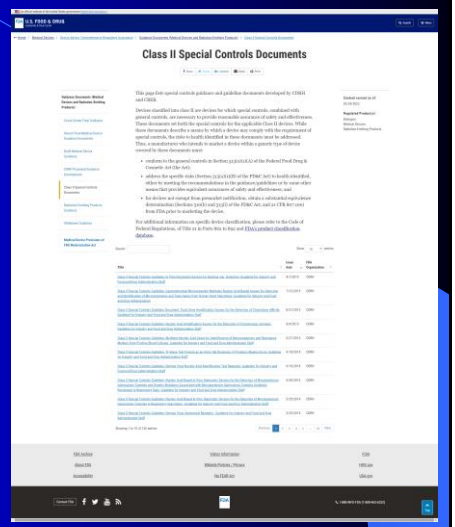
- ✓ Guidance document database here
- ✓ Rec Consensus Standards database here
- ✓ CDRH List of 126 Special Controls here
  - Ex: Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters - Class II Special Controls here

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…

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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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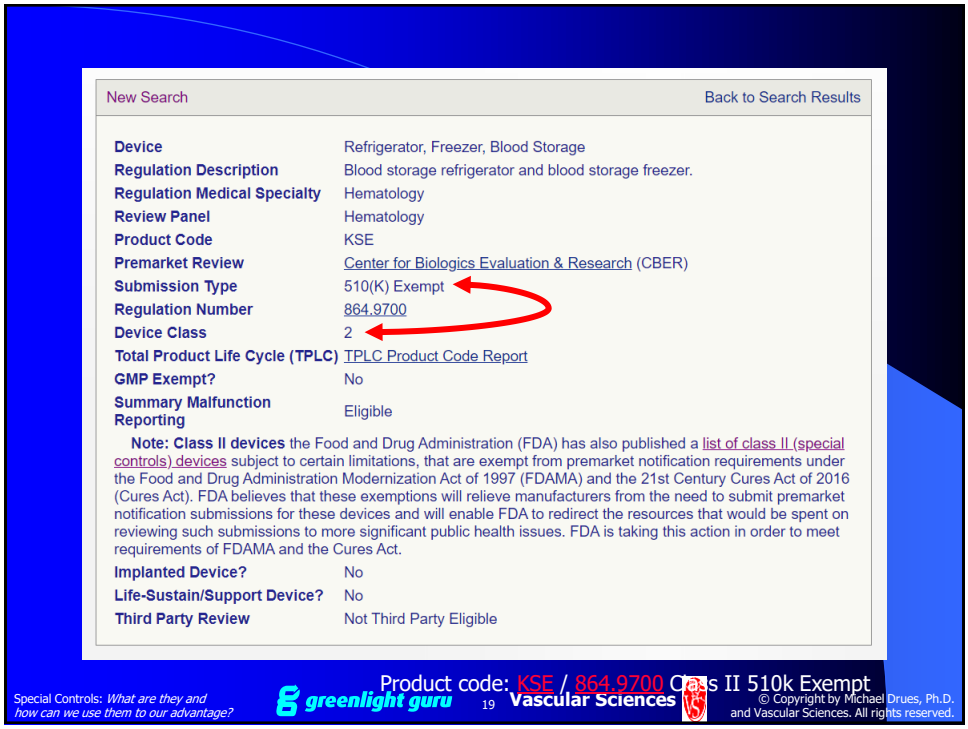

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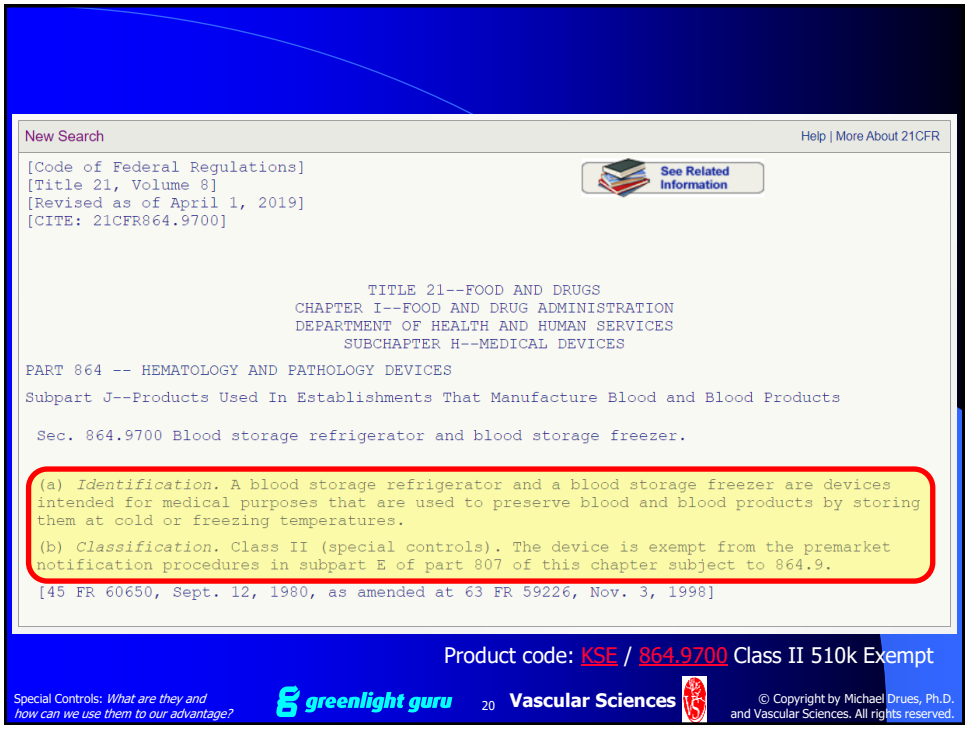

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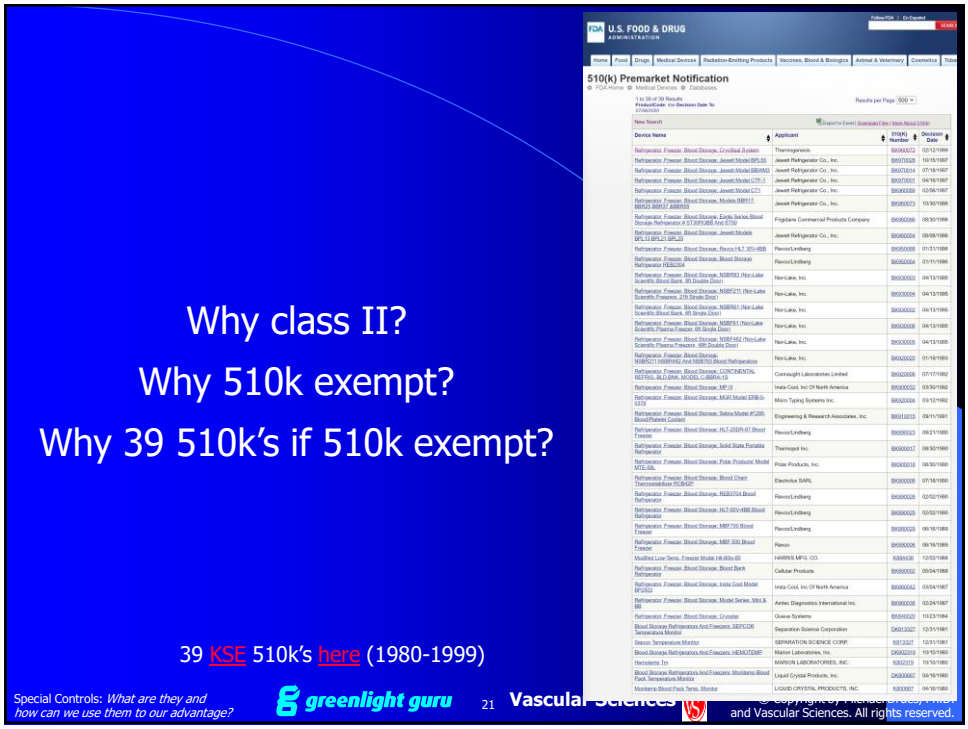

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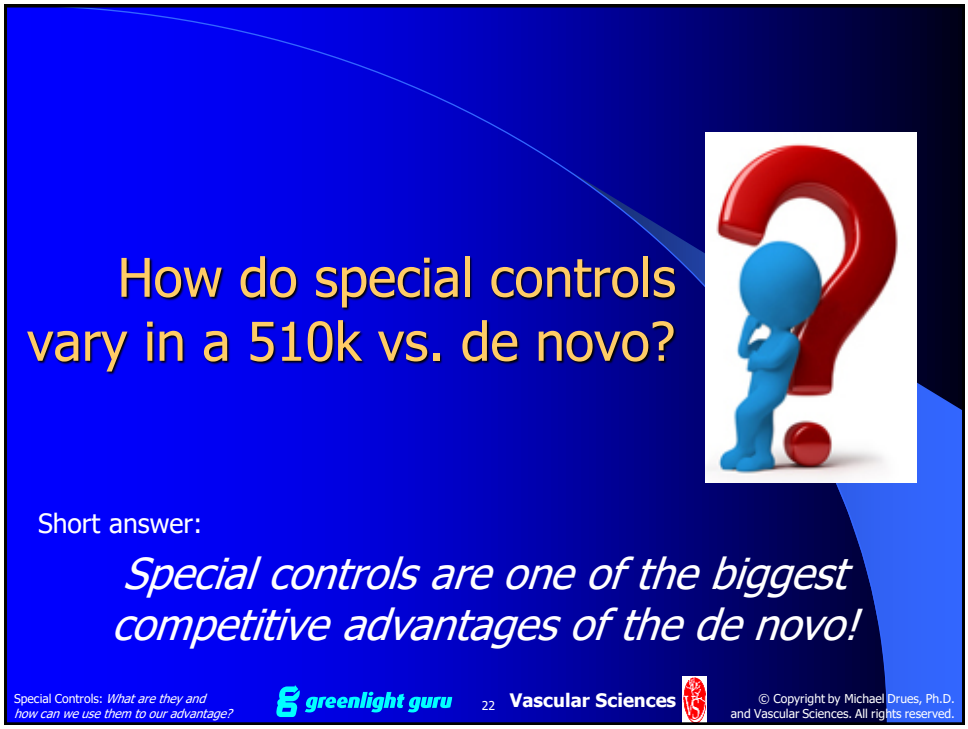

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Using Regulation as a Competitive Advantage

"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)


It's the Law

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

By Michael A. Swit, 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 patent 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)[1] 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 30 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,"[2] 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 ill because, temporally, 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[3]—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's reform efforts, culminating in the 1997 *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 linking 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[4] 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, *de novo*—Latin for "out of" 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,[5] 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 risks can be controlled via Class II special controls or Class I general strictures.[6]

The Logistics of the *de Novo* Petition Process

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

32 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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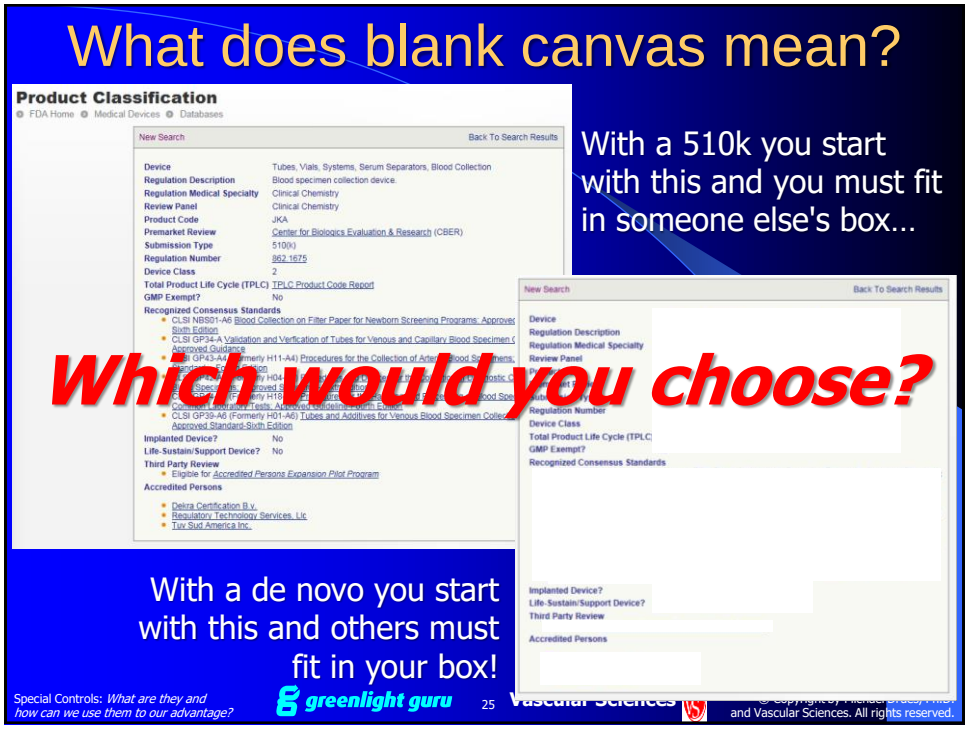

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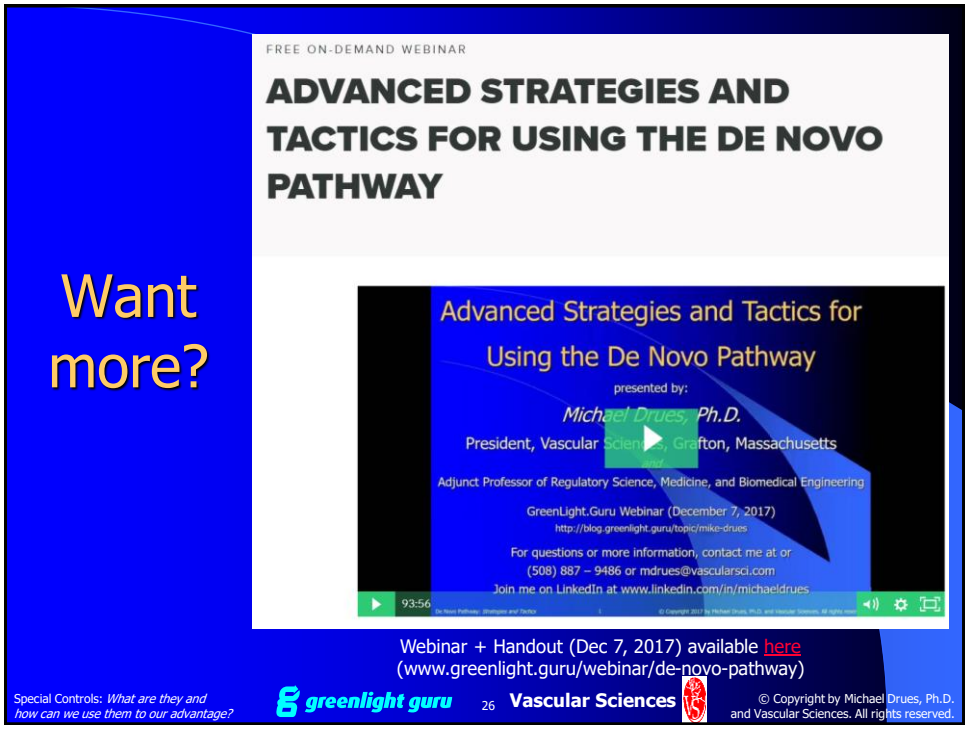

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Guest Editorial: The de novo pathway - Strategies and Tactics to Use and Avoid

http://www.globalregulatorypress.com/

Abstract available here.

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

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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?

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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

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:

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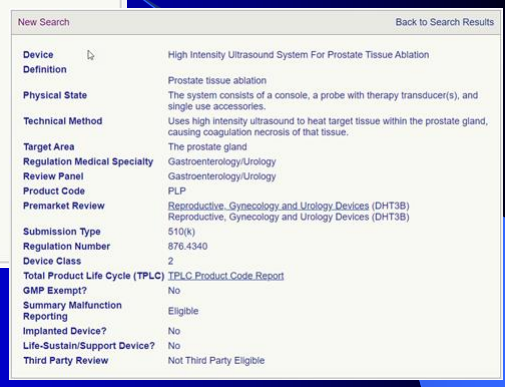
Case Study: Sonablate

New Search | Back to Search Results

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



New Search | Back to Search Results

Device Definition	High Intensity Ultrasound System For Prostate Tissue Ablation
	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

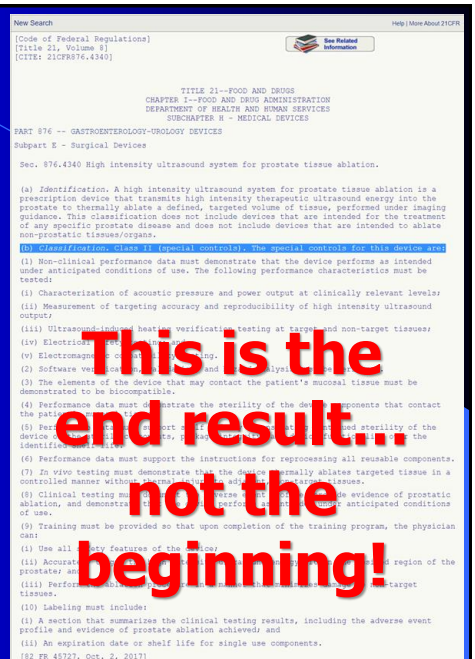
Note: in some cases, special controls are listed in the Product Code description. In this example, they are listed in the Code of Federal Regulations description (876.4340).

Always important to check both!

Notes from Redacted Submission:

1. Summary of "proposed" special controls pp. 67-68
2. Details of "proposed" special controls p.69+
3. **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
4. 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! ☺



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[Code of Federal Regulations]
[Title 21, Volume 8]
[CITE: 21CFR876.4340]

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 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) *Classification.* Class II (special controls). The special controls for this device are:

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

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

(ii) Measurement of targeting accuracy and reproducibility of high intensity ultrasound output;

(iii) Ultrasound-induced heating verification testing at target and non-target tissues;

(iv) Electrical

(v) Electromagnetic

(2) Software ver

(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

(5) Per

device

identified

(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

(8) Clinical testing must

ablation, and demonstrate

of use.

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

(i) Use all

(ii) Accurate

prostate; and

(iii) Perform

tissues.

(10) Labeling must include:

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

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

[82 FR 45727, Oct. 2, 2017]

This is the end result… not the beginning!

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With Power Comes Responsibility

feature | Check for updates

PATENTS

The FDA De Novo medical device pathway, patents and anticompetition

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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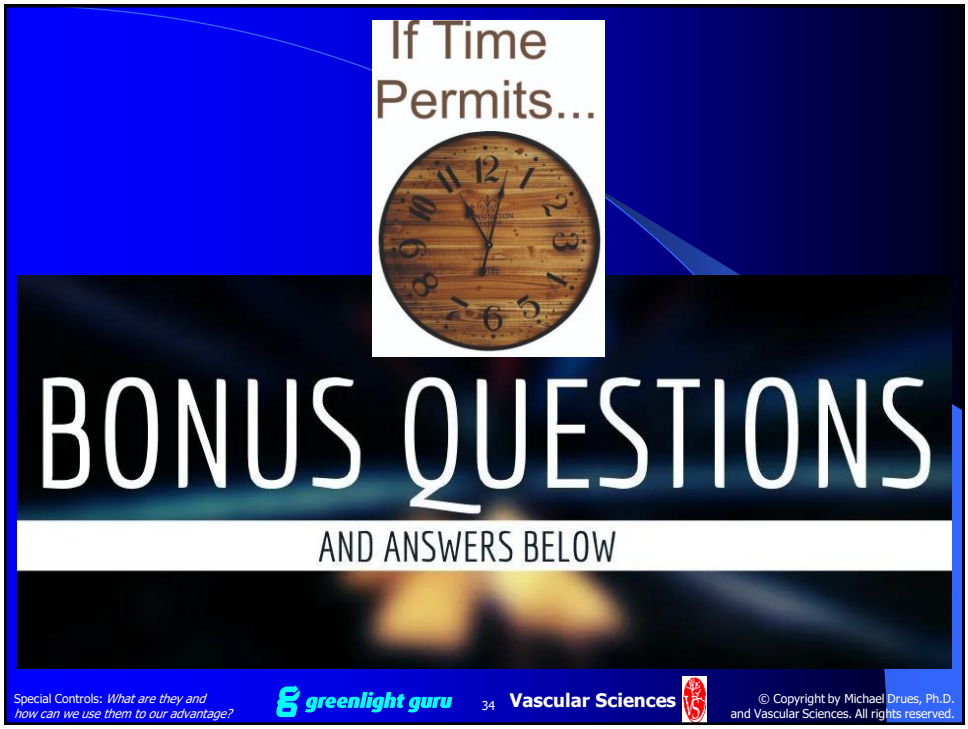

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Special Controls:

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…

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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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GreenLight.Guru Webinar (May 19, 2022)

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

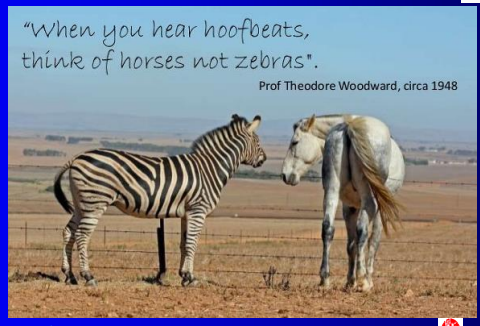
Special Controls:

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

Similar question:

Can a new 510k create a new product code

Remember…



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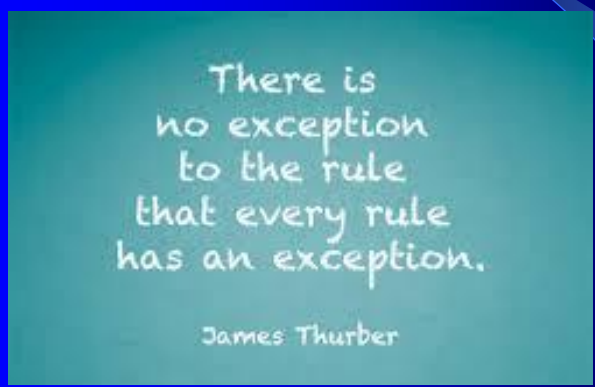
Rules and Exceptions

Average regulatory professionals know the rules…
better regulatory professionals know the exceptions…
the best regulatory professionals know the exceptions to the exceptions!



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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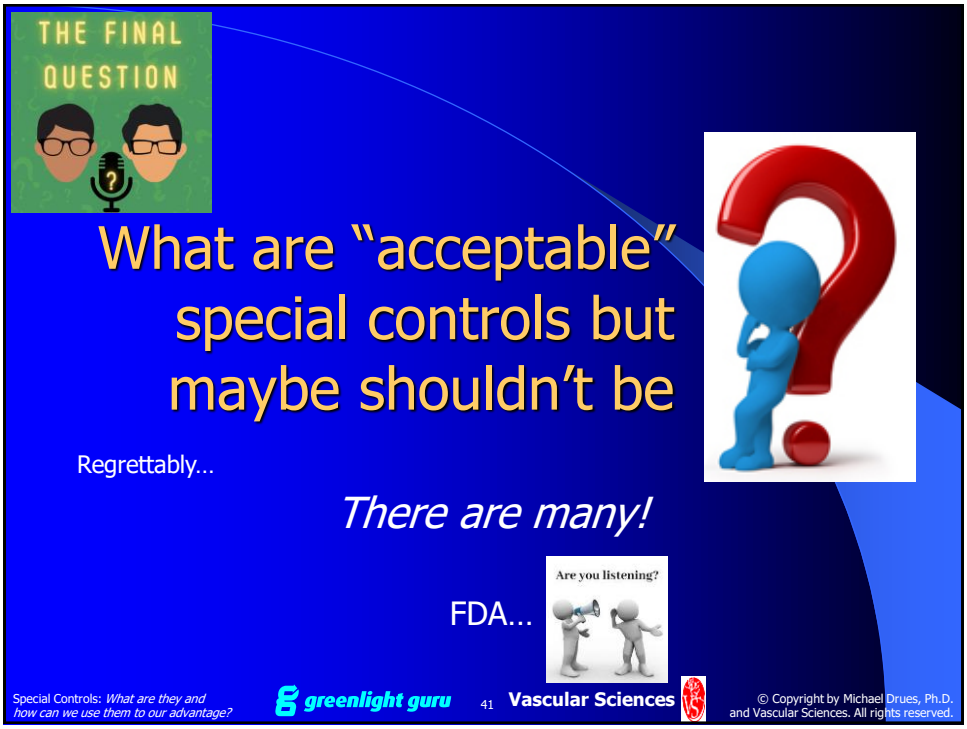

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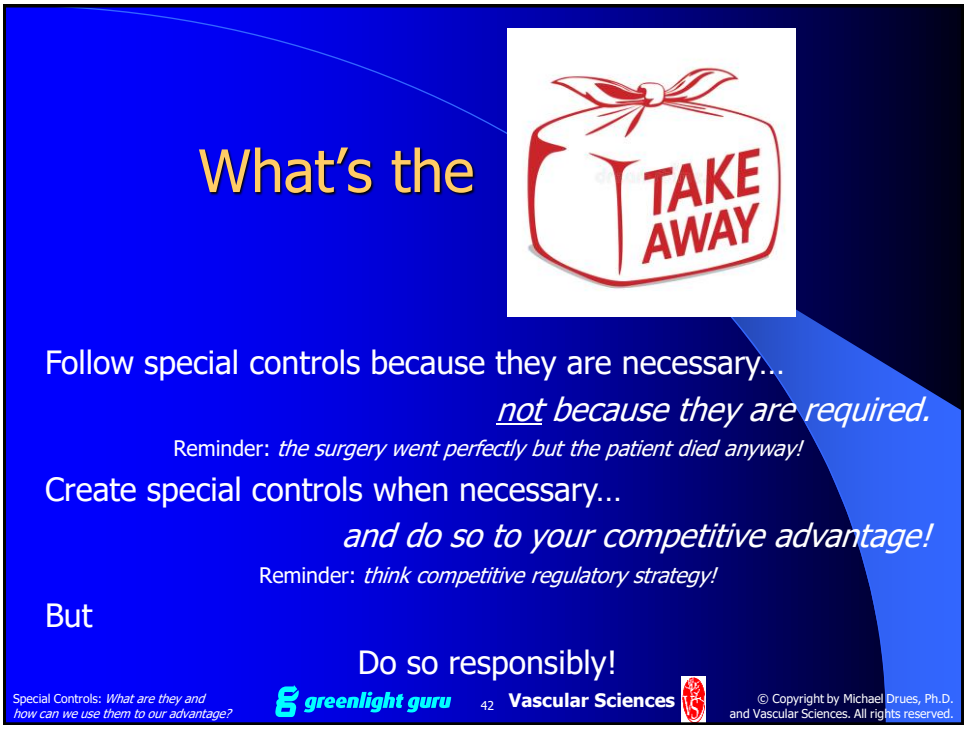

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Special Controls:

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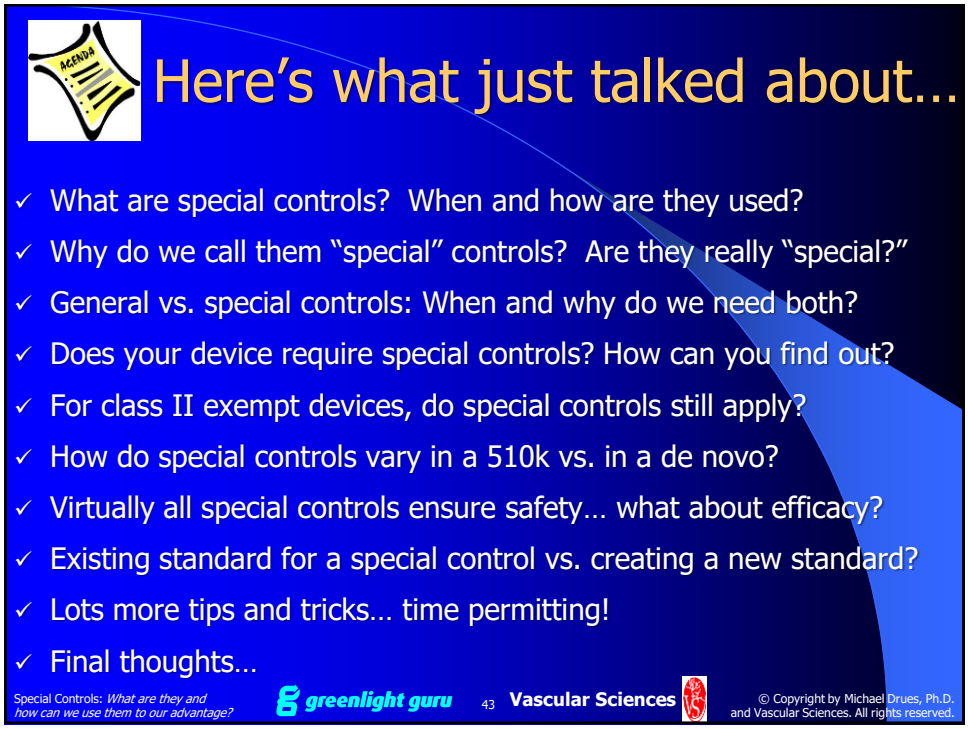

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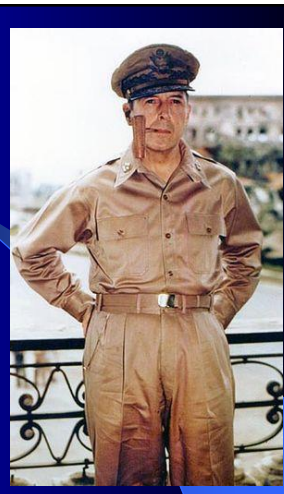
Special Controls:

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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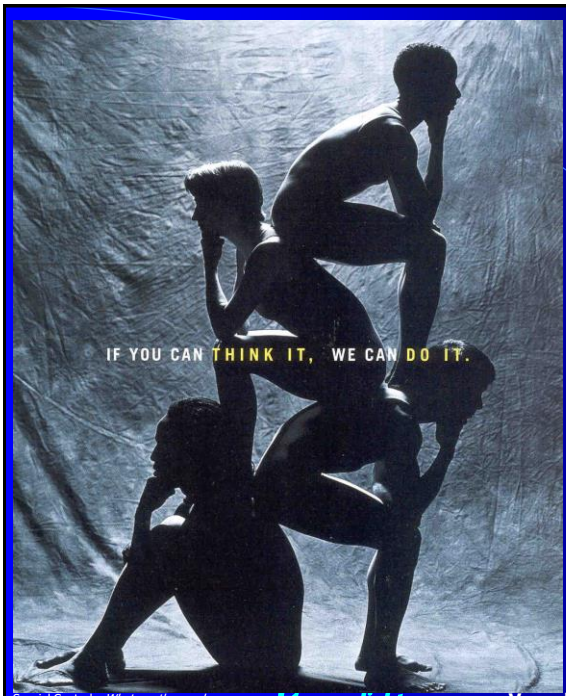
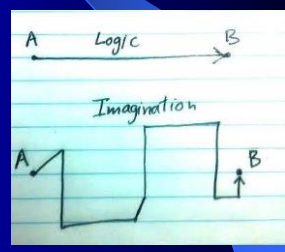


"Imagination is more important than knowledge, for while knowledge points to all there is, imagination points to all that can be."

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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