The "New" 510k:

How do you show substantial equivalence without using a predicate?

presented by:

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Carlsbad, California

and

Adjunct Professor of Regulatory Science, Medicine and Biomedical Engineering

Cornell University Graduate Dept. of Biomedical Engineering

GreenLight.Guru (November 4, 2021)

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

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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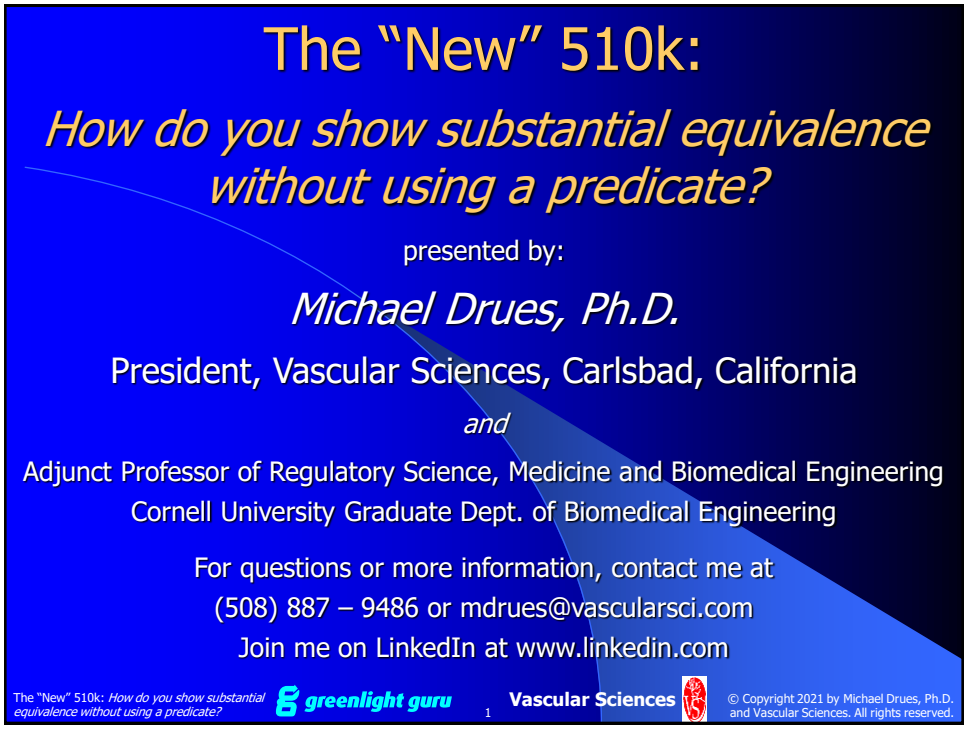

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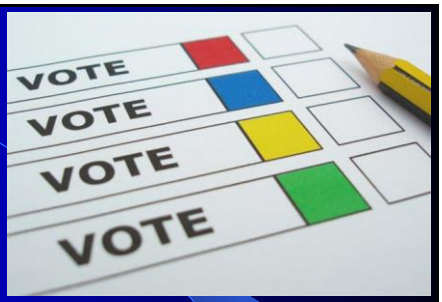
Before we begin…

Polling Question



Have you worked on a 510k device in the past? (y/n)

Do you currently work on a 510k device and if so, what type?

Traditional / Special / Abbreviated / More than One / None or Don't Know

Are you considering using the "Safety and Performance Based Pathway" now or in the future? (y/n)

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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 is the sp510k and why was it created?
- ✓ How is the sp510k similar and different to other types of 510k's?
- ✓ How do you show substantial equivalence without using a predicate?
- ✓ What are the advantages and disadvantages of using the sp510k?
- ✓ What types of devices are eligible for the sp510k?
- ✓ What is the future of the sp510k? Will it gain popularity?
- ✓ Lots more tips and tricks… time permitting!
- ✓ Final thoughts…

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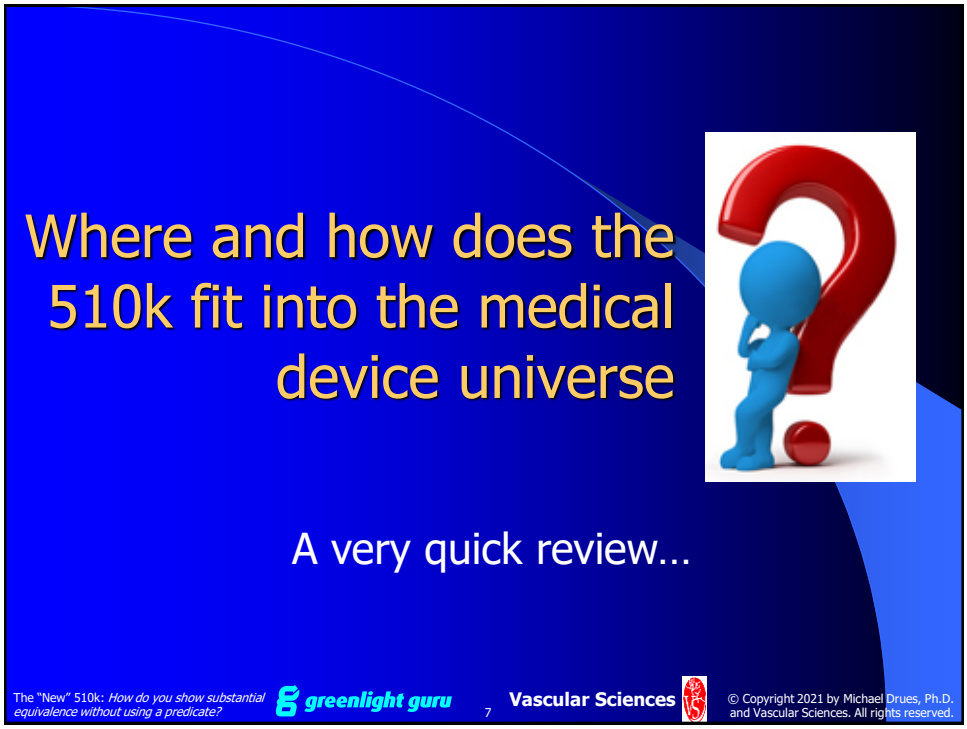

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The "New" 510k:

How do you show substantial equivalence without using a predicate?

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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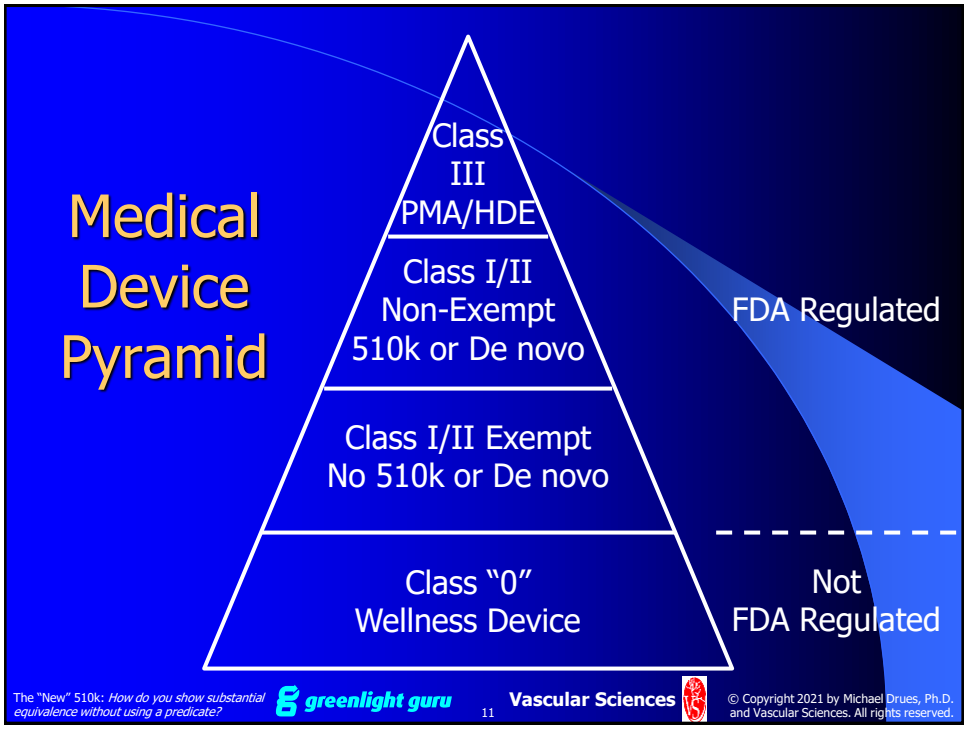

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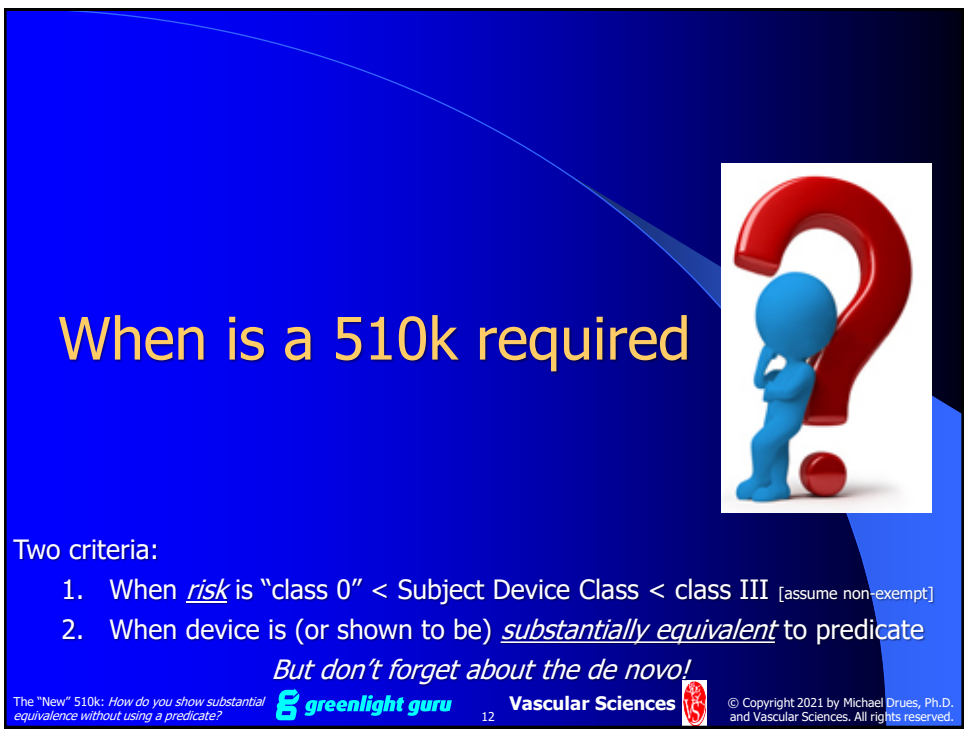

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What are the two most important components of a successful 510k

Substantial Equivalence Argument and Risk Mitigation Strategy

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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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The "New" 510k:

How do you show substantial equivalence without using a predicate?

An exception to the rule?

"That 510(k) pathway provision, which was meant as an exception, in essence, a little loophole...

That exception became the rule.

So the vast majority of devices today, regrettably, are regulated under this framework."

The Bleeding Edge (Netflix, July, 2018)

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What is the sp510k and why was it created?

Claim: *The "new" Safety & Performance Based Pathway" is an expansion of abbreviated 510k for certain "well understood" devices.*

Could it be an "update" to the a510k?

Could it be politics?

Or could it be so many people screw up SE?

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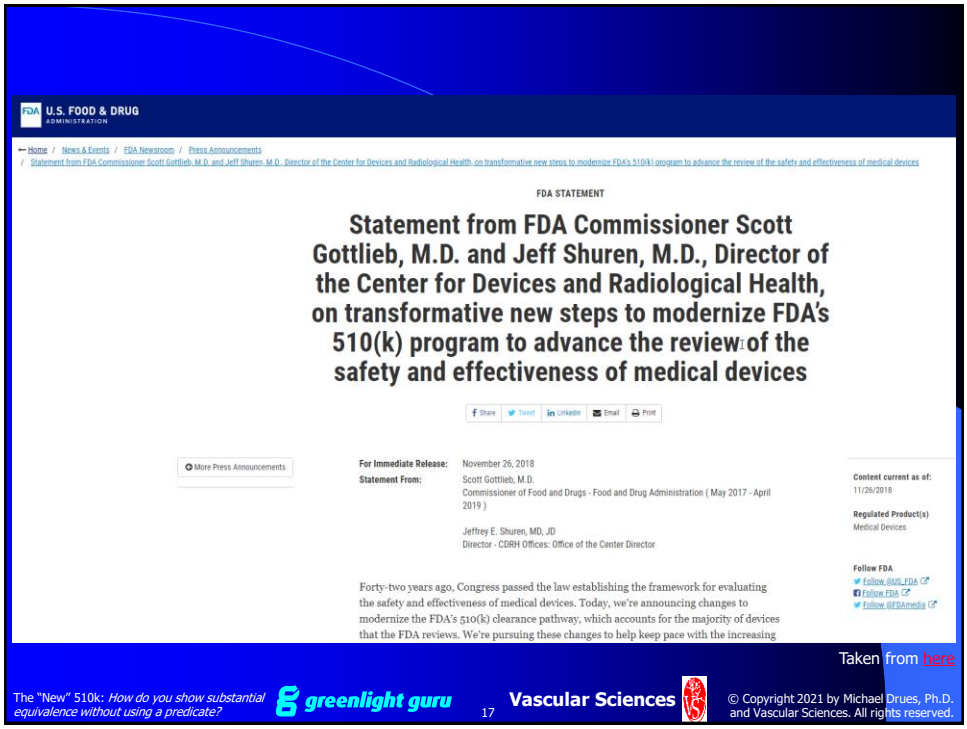

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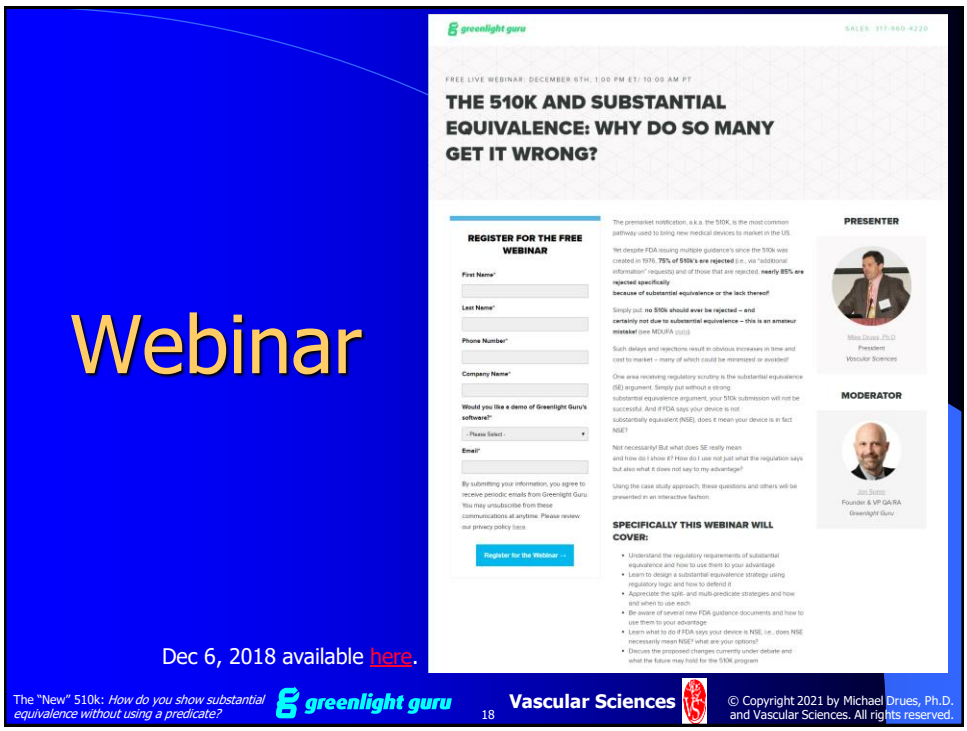

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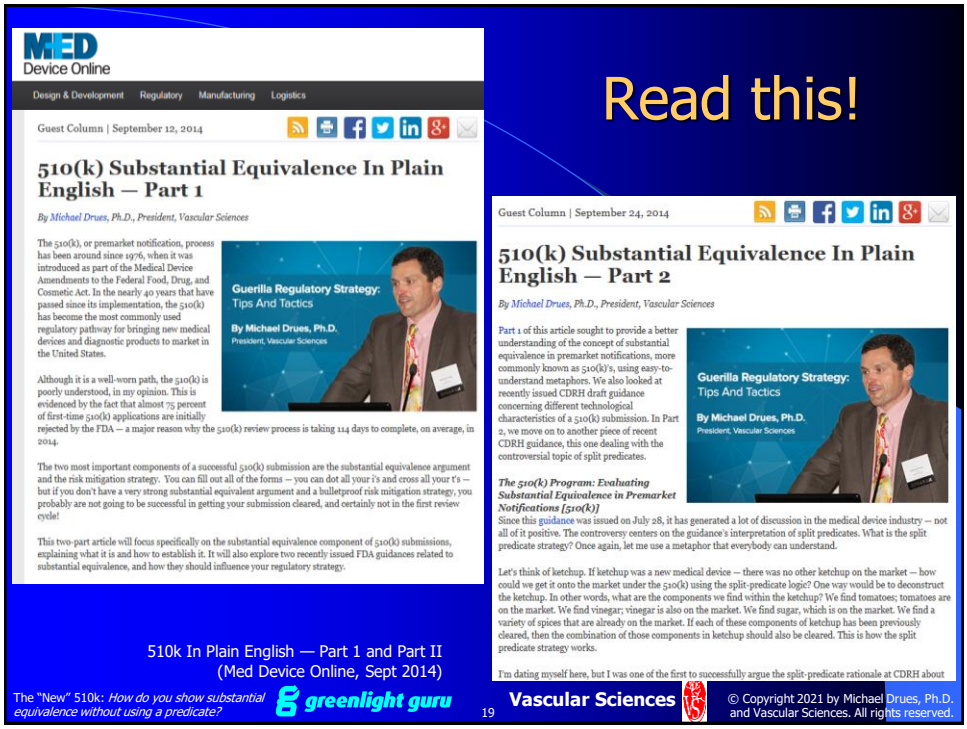

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The "New" 510k:

How do you show substantial equivalence without using a predicate?

How consistent is substantial equivalence

Short answer: *not very!*

Informal Survey:

12 current/former CDRH reviewers and industry RA professionals with varying levels of experience were presented with same hypothetical subject & predicate devices…

Results: 5 said SE and 7 said NSE

After 45 years of playing the 510k/SE game… what does that say?

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How is the sp510k similar and different to other types of 510k's?

All 510k's rely on substantial equivalence…
but in very different ways!

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The "New" 510k:

How do you show substantial equivalence without using a predicate?

Types of 510k's

- ✓ Traditional – show SE to another device
- ✓ Special – show SE to pre-changed device
- ✓ Abbreviated – show SE to standard

Note:

The "New 510k Paradigm" is >20 years old!

Do we need anything else?

- ✓ Safety and Performance 510k

Created in 2018 but what is it?

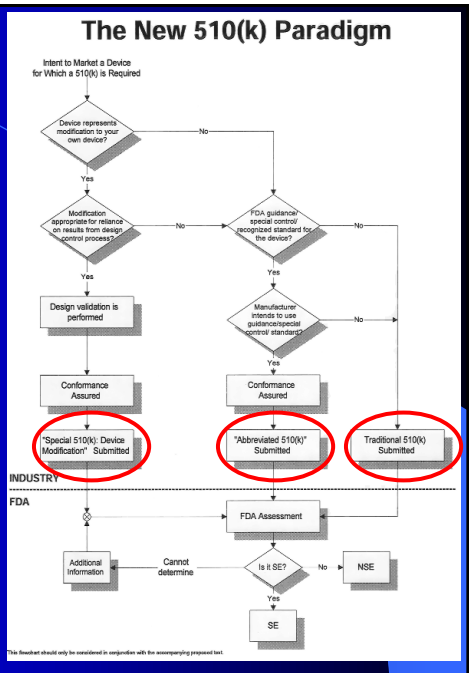
The Safety and Performance Based 510(k): A New Pathway for Regulatory Submission (Med Device On-line, March, 2019) here.

- ✓ Catch-Up 510k

Still doesn't exist… formally. What is it?

- ✓ Anything else?

The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications ("Final" Guidance, Mar, 1998) here.



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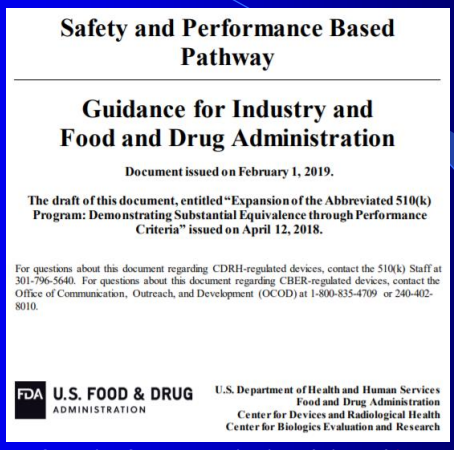
"New" Safety and Performance 510k



Safety and Performance Based Pathway

Guidance for Industry and Food and Drug Administration

Document issued on February 1, 2019.

The draft of this document, entitled "Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria" issued on April 12, 2018.

For questions about this document regarding CDRH-regulated devices, contact the 510(k) Staff at 301-796-5640. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Safety and Performance Based Pathway (Feb, 2019) here.

Is the "new" $sp510k_{2018}$ substantially equivalent to $a510k_{1998}$?

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The "New" 510k:

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Catch-Up 510k

- ✓ What is a catch-up 510k?
  Hint: *Medical device development is often an iterative process (unlike drugs)!*
- ✓ Why do we need it?
  Hint: *What is change creep?*
- ✓ When should we use it?
  Hint: *before or after getting a 483? maybe even a warning letter?*
- ✓ Given there is no catch-up 510k, how would you use it?
  Hint: ***Don't use regulation as an excuse to hold you back!***

Reference: "The "Catch-Up" 510(k) — A Submission Often Overlooked" (RAPS, Jan, 2016) here.

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What are the criteria for the sp510k

Consider using safety and performance-based pathway if:

1. **Classification:** device is ≤ class II
2. **Labeling:** device has "same" indications for use/intended use (both) as predicate
3. **Technology:** device has "same" technological characteristics as predicate

– or –

3. **Technology:** device has different technological characteristics that do not raise new/additional questions of safety and effectiveness nor do they create new/increased risks

– and –

4. **Performance Criteria:** device meets all FDA-identified performance criteria (per applicable guidance)

If any of above are not met, sp510k is contraindicated → consider t/s/a510k, de novo, PMA, etc.

Reminders/Recommendations:

- ✓ sp510k is voluntary not mandatory – can always demonstrate SE the "old fashioned" way
- ✓ do not show substantial equivalence to a specific device i.e., predicate rather to a standard
- ✓ however, still need predicate for non-performance purposes, i.e., labeling and technology
- ✓ still could get NSE with a sp510k – *how?* Mitigate risk via pre-sub!

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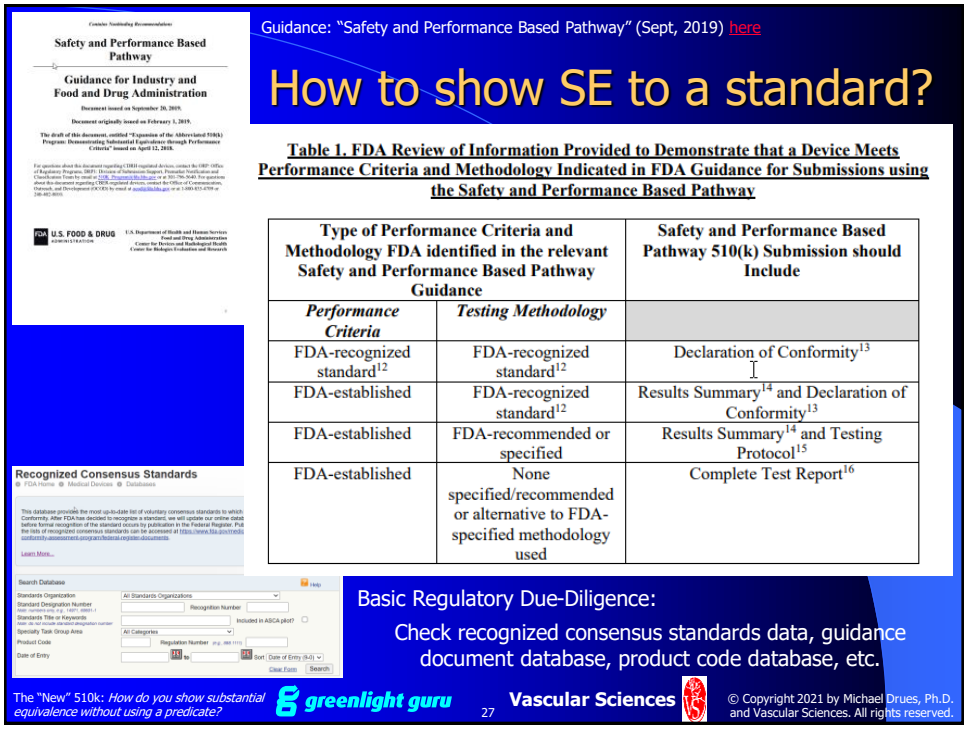

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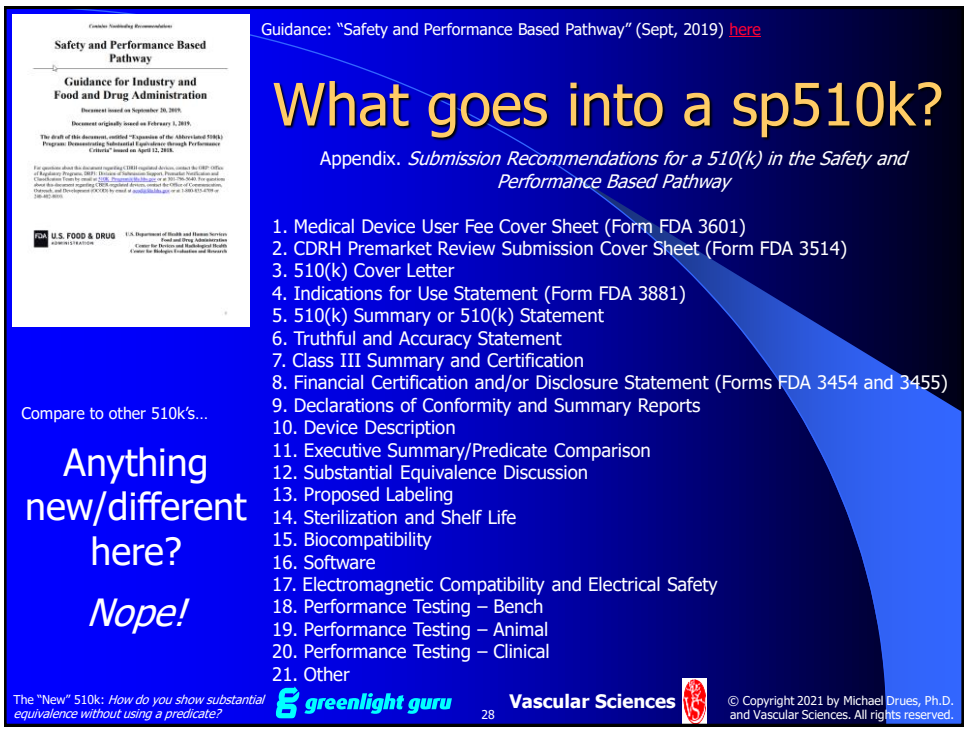

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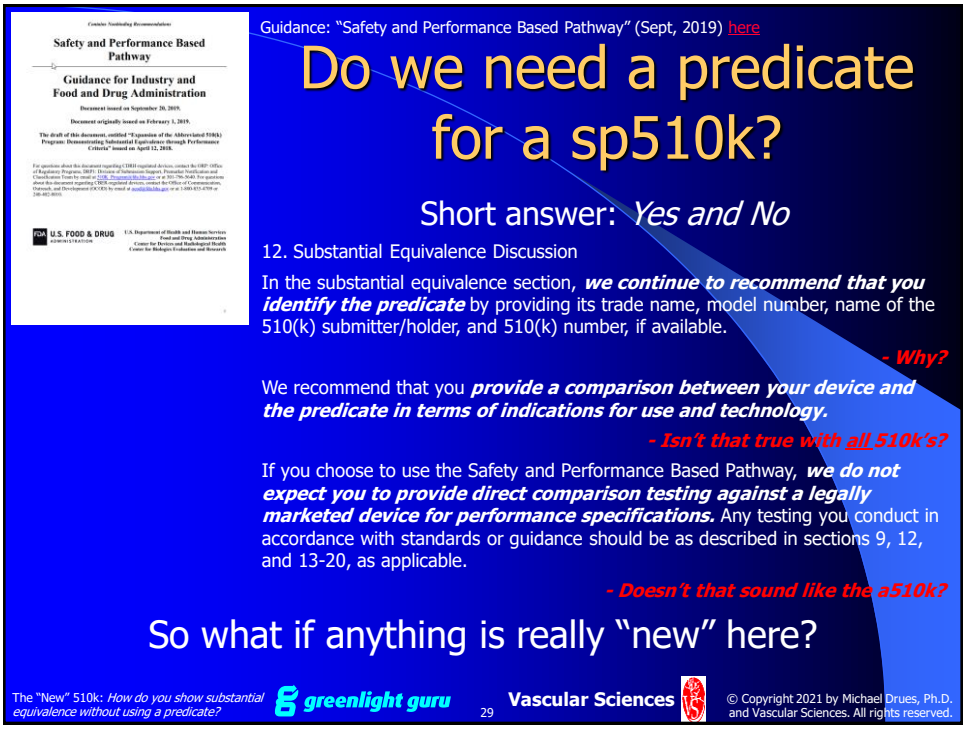

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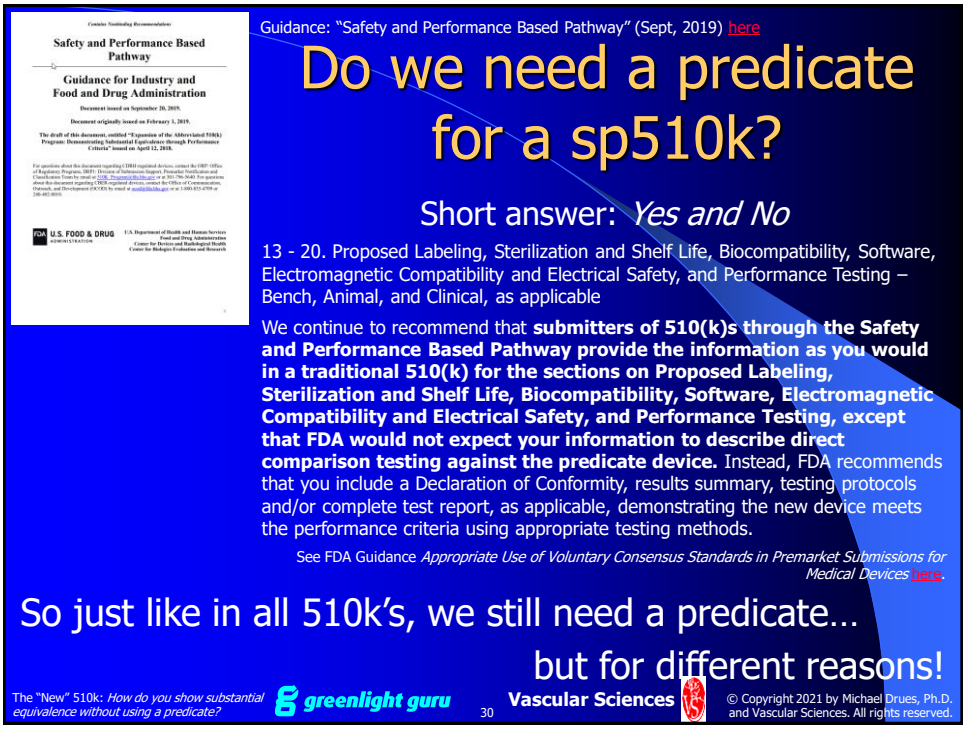

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What does a sp510k cost

What are the MDUFA User Fees associated with a 510(k) using the Safety and Performance Based Pathway?

All 510(k) submission types including those submitted under the Safety and Performance Based Pathway require the 510(k) review fee. Information on how to submit the fee can be found at Medical Device User Fees.

FDA Website: *Safety and Performance Based Pathway* (Nov, 2021) here

So how much $$$ is it?

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Medical Device User Fee Act (MDUFA) 2022

User Fees for FY2022

Annual Establishment Registration Fee: $5,672

All establishments must pay the establishment registration fee. There are no waivers or reductions for small establishments, businesses, or groups.

Other fees for Fiscal Year 2022 (October 1, 2021 through September 30, 2022) are:

Application Type	Standard Fee	Small Business Fee†
510(k)	$12,745	$3,186
513(g)	$5,061	$2,530
PMA,PDP,PMR,BLA	$374,858	$93,714
De Novo Classification Request	$112,457	$28,114
Panel-Track Supplement	$281,143	$70,286
180-Day Supplement	$112,457	$14,057
Real-Time Supplement	$26,240	$6,560
BLA Efficacy Supplement	$374,858	$93,714
30-Day Notice	$11,998	$2,999
Annual Fee for Periodic Reporting on a Class III device (PMAs,PDPs, and PMRs)	$13,120	$3,280

No financial incentive for sp510k... Why not?!? ☹

† ***Small Business Fee:*** *For businesses certified by the Center for Devices and Radiological Health (CDRH) as a small business..*

‡ ***510(k) Fees:*** *All types of 510(k)s (Traditional, Abbreviated, and Special) are subject to the user fee. However, there is no user fee for 510(k)s submitted to the FDA on behalf of an FDA-accredited third-party reviewer.*

FY2022 MDUFA User Fees available here.

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The "New" 510k:

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How do you show substantial equivalence *without* using a predicate?

Short answer: *By showing equivalence to a standard!*

But you still need a predicate anyway… *ironic, isn't it?*

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What are the advantages and disadvantages of the sp510k?

Positives

- ✓ more objective – less subjective
- ✓ more predictable for sponsor and FDA
- ✓ "simpler" (more well defined) submission but NOT lower regulatory burden
- ✓ less prep time for sponsor and FDA (theoretically)

Negatives

- ✓ no RTA checklist… yet – *but do we need one?*
- ✓ should be less time… but its not! ☹
- ✓ should be less money… but its not! ☹

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The "New" 510k:

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What types of devices are eligible for the sp510k?

It's a very short list… *at least for now!*

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What device types are appropriate for the sp510K?

What's available now? →

What if your device is not on the list? →

What's in the que? →

FDA Website: *Safety and Performance Based Pathway* (Nov, 2021) here

The Safety and Performance Based Pathway is appropriate when the FDA has determined:

- The new device has the same indications for use as, and technological characteristics that do not raise different questions of safety and effectiveness than the identified predicate; and — ***DUH!***
- The new device meets all the FDA-identified performance criteria.

If any of the above factors are not met, the submitter [illegible] Traditional, Special or Abbreviated 510(k). — ***important new part***

The following final guidances identify performance criteria and testing methodologies for device types that are appropriate for this pathway:

- Spinal Plating Systems
- Orthopedic Non-Spinal Metallic Bone Screws and Washers
- Magnetic Resonance Receive-Only Coils
- Cutaneous Electrodes for Recording Purposes
- Conventional Foley Catheters

The FDA will continue to issue draft and final guidance(s) to apply this Safety and Performance Based Pathway to additional types of devices with corresponding FDA-identified performance criteria. Industry may suggest device types for which the FDA should consider identifying performance criteria. For example, industry may suggest devices for which there are comprehensive FDA-recognized consensus standards. We encourage industry and other stakeholders to submit evidence-based suggestions on what the performance criteria should be for eligible device types. Input can be provided using the docket number FDA-2018-D-1387 at www.regulations.gov.

The FDA issued draft guidance identifying performance criteria and testing methodologies for the following device types. Once these guidance documents are finalized, submitters will have the option to use the safety and performance based pathway for these device types.

- Soft (Hydrophilic) Daily Wear Contact Lenses
- Denture Base Resin
- Facet Screw Systems

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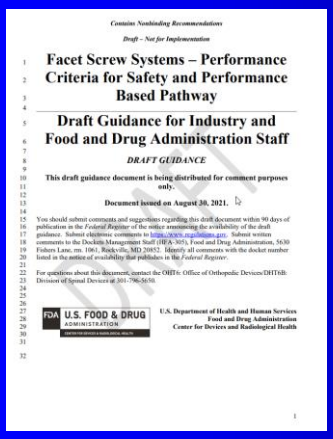
Where are we headed with this?



Contains Nonbinding Recommendations

Draft – Not for Implementation

Facet Screw Systems – Performance Criteria for Safety and Performance Based Pathway

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on August 30, 2021.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact the OHT1: Office of Orthopedic Devices/DHT6B: Division of Spinal Devices at 301-796-5650.

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U.S. Department of Health and Human Services
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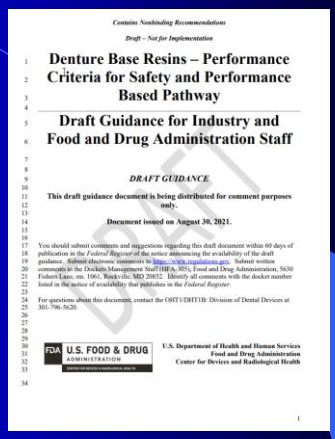
CDRH Guidance (Aug, 2021) here



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For questions about this document, contact the OHT1:DHT1B: Division of Dental Devices at 301-796-5620.

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CDRH Guidance (Aug, 2021) here

Do we want specific guidance for all "well established" devices?

How long will that take? What will it cost?

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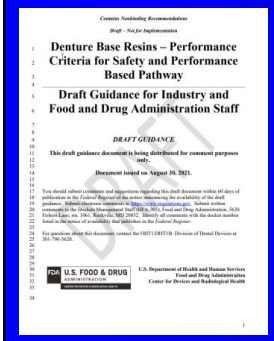
What's in these guidance's?



Contains Nonbinding Recommendations

Draft – Not for Implementation

Denture Base Resins – Performance Criteria for Safety and Performance Based Pathway

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on August 30, 2021.

U.S. FOOD & DRUG ADMINISTRATION

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

CDRH Guidance (Aug, 2021) here

Mechanical Bench Testing

1. **Test name:** Ultimate flexural strength
   Methodology: ISO 20795-1 *Dentistry – Base polymers – Part 1: Denture base polymers*
   Performance Criteria:
   Types 1, 3, 4, and 5 polymers: ≥ 65 MPa
   Type 2 polymers: ≥ 60 MPa
   Performance Criteria Source: ISO 20795-1 (2013) *Dentistry – Base polymers – Part 1: Denture base polymers*
   Submission Information: DoC

2. **Test name:** Flexural modulus
   Methodology: ISO 20795-1 *Dentistry – Base polymers – Part 1: Denture base polymers*
   Performance Criteria:
   Types 1, 3, 4, and 5 polymers: ≥ 2000 MPa
   Type 2 polymers: ≥ 1500 MPa
   Performance Criteria Source: ISO 20795-1 (2013) *Dentistry – Base polymers – Part 1: Denture base polymers*
   Submission Information: DoC

3. **Test name:** Stress intensity factor
   Methodology: ISO 20795-1 *Dentistry – Base polymers – Part 1: Denture base polymers*
   Performance Criteria: Types 1-5 polymers: ≥ 1.9 MPa • $m^{1/2}$
   Performance Criteria Source: ISO 20795-1 (2013) *Dentistry – Base polymers – Part 1: Denture base polymers*
   Submission Information: DoC

4. **Test name:** Fracture work
   Methodology: ISO 20795-1 *Dentistry – Base polymers – Part 1: Denture base polymers*
   Performance Criteria: Types 1-5 polymers: ≥ 900 J/m^2
   Performance Criteria Source: ISO 20795-1 (2013) *Dentistry – Base polymers – Part 1*

Tick the testing boxes and we're done… at least in terms on SE.

Don't forget the other stuff!

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GreenLight.Guru Webinar (November 4, 2021)

www.greenlight.guru/webinar/new-510k-how-do-you-show-substantial-equivalence-without-a-predicate

The "New" 510k:

How do you show substantial equivalence without using a predicate?

What is the future of the sp510k? Will it gain popularity?

Short answer:

It depends on you!

i.e., will you make sp510k submissions? Will you make suggestions for new categories?

Or will the sp510k remain one of the esoteric pathways to market like the a510k?

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Let's put this in regulatory terms…

Can the claims of the sp510k be supported

Claim: The "new" Safety & Performance Based Pathway" is an *expansion* of abbreviated 510k for certain "well understood" devices.

So is sp510k a "label expansion" based on the a510k (i.e., predicate)?

Is sp510k NSE to a510k → De novo?

Or is sp510k SE to a510k and thus another "me-too" 510k?

Note: *all puns intended!* ☺

and now

Deep thoughts…

with Jack Handy (Saturday Night Live)

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on the sp510k

Positives

- ✓ more objective – less subjective
- ✓ more predictable for sponsor and FDA
- ✓ "simpler" (more well defined) submission but NOT lower regulatory burden
- ✓ less prep time for sponsor and FDA (theoretically)

Negatives

- ✓ no RTA checklist… yet – *but do we need one?*
- ✓ should be less time… but its not! ☹
- ✓ should be less money… but its not! ☹

Mike's Take

- ✓ sp510k substantially equivalent to a510k (pun intended) – *so do we need it?*
- ✓ few meaningful incentives… *but they could be easily created!*
- ✓ consider using if device / technology is in "accepted" list – *but confirm via pre-sub first!*
- ✓ make suggestions on what devices / technologies to add
- ✓ overall all… mixed bag

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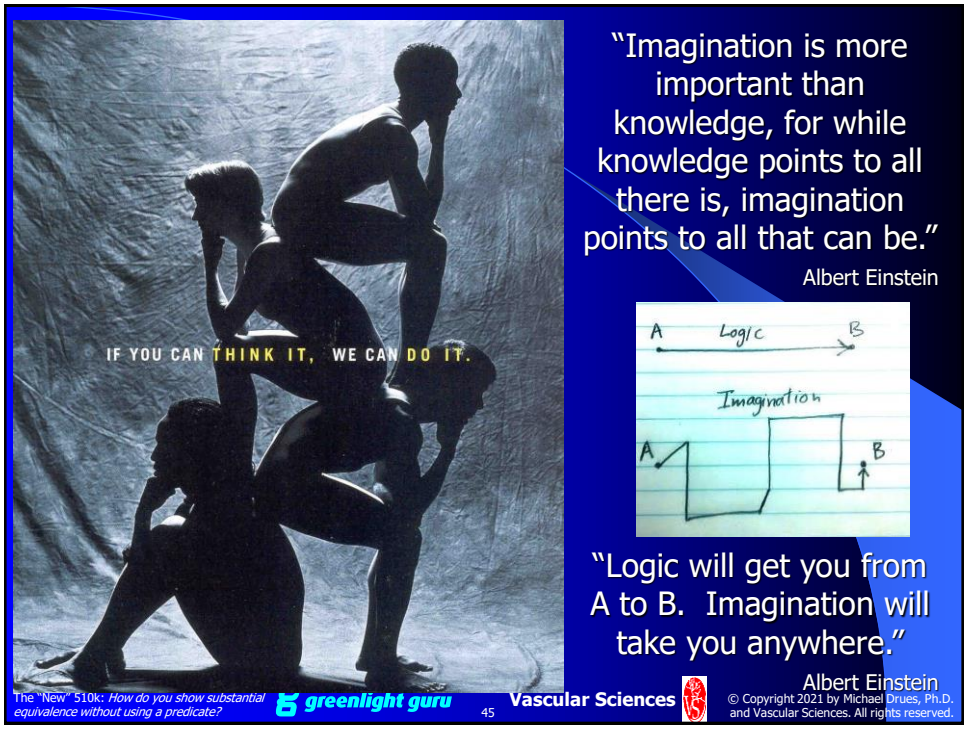

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