

The “New” 510k:

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

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 (November 4, 2021)

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

For questions or more information, call
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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 & 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 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,

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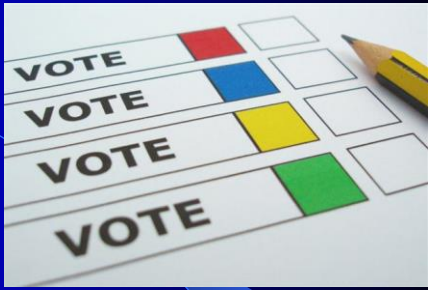
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Before we begin...

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?



Guerilla Regulatory Strategy:
Tips And Tactics

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


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



Where and how does the 510k fit into the medical device universe



A very quick review...

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MICHAEL DRUES, PH.D.
President at Vascular Sciences

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



Remember,

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



Short answer:

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

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



Not so short list:

1. Wellness Exemption
2. Class I Exempt / Class II Exempt
3. Pre-Market Notification a.k.a. 510k
4. De Novo
5. Pre-Market Approval (PMA)
6. Humanitarian Device Exemption (HDE)
7. Custom Device Exemption (CDE)
8. Expanded Access Pathway
9. Emergency Use Authorization (EAU)

Plus:

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

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

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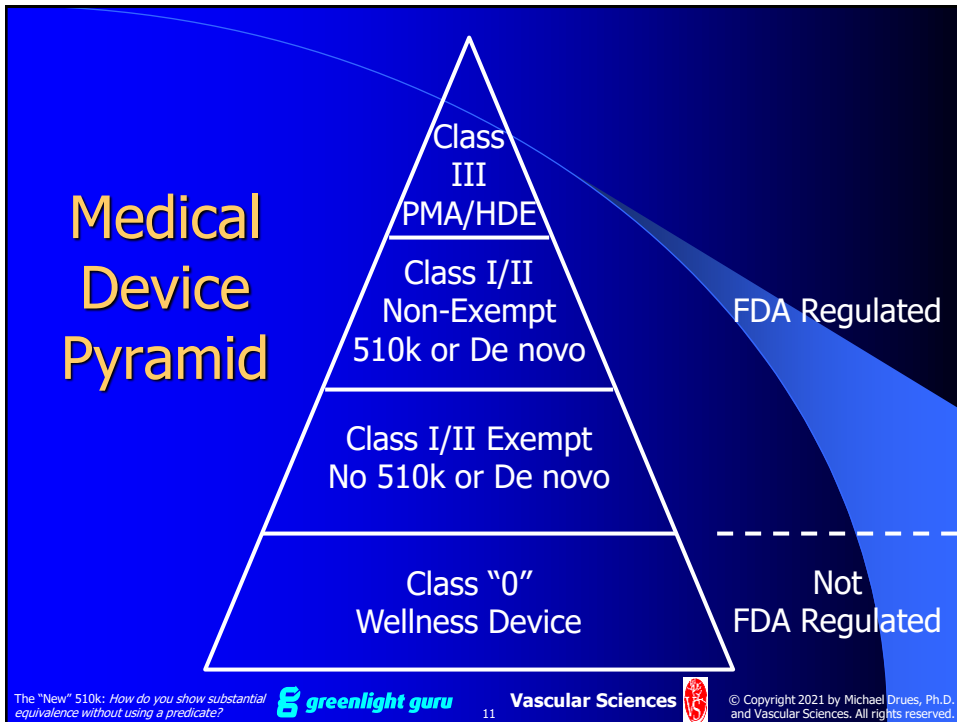
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The slide has a blue background with a large red 3D question mark on the right. A small blue 3D figure is standing next to the question mark, looking up at it.

When is a 510k required

Two criteria:

1. When risk is "class 0" < Subject Device Class < class III [assume non-exempt]
2. When device is (or shown to be) substantially equivalent to predicate

But don't forget about the de novo!

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How do you show substantial equivalence without using a predicate?

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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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."




DR. DAVID KESSLER
FDA Commissioner, 1990-1997

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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The screenshot shows the FDA's official statement on the modernization of the 510(k) program. The title is "Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on transformative new steps to modernize FDA's 510(k) program to advance the review of the safety and effectiveness of medical devices". The statement is dated November 26, 2018. It mentions that the FDA is pursuing changes to help keep pace with the increasing number of medical devices. The statement is taken from [here](#).

U.S. FOOD & DRUG ADMINISTRATION

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Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on transformative new steps to modernize FDA's 510(k) program to advance the review of the safety and effectiveness of medical devices

FDA STATEMENT

Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on transformative new steps to modernize FDA's 510(k) program to advance the review of the safety and effectiveness of medical devices

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For Immediate Release: November 26, 2018
Statement From: Scott Gottlieb, M.D., Commissioner of Food and Drugs - Food and Drug Administration (May 2017 - April 2019)
Jeffrey E. Shuren, MD, JD
Director - CDRH Offices: Office of the Center Director

Content current as of: 11/26/2018

Regulated Product(s): Medical Devices

Follow FDA
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Forty-two years ago, Congress passed the law establishing the framework for evaluating the safety and effectiveness of medical devices. Today, we're announcing changes to modernize the FDA's 510(k) clearance pathway, which accounts for the majority of devices that the FDA reviews. We're pursuing these changes to help keep pace with the increasing

Taken from [here](#)

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The screenshot shows the registration page for a webinar titled "THE 510K AND SUBSTANTIAL EQUIVALENCE: WHY DO SO MANY GET IT WRONG?". The webinar is scheduled for December 6th, 1:00 PM ET to 10:00 AM PT. The page includes a registration form with fields for First Name, Last Name, Phone Number, and Company Name. It also features a "REGISTER FOR THE FREE WEBINAR" button. The page lists the presenter, Mrs. Susan J. Liu, President of Vascular Sciences, and the moderator, Jeff Shuren, Founder & VP QA/RA of Greenlight Guru. The webinar will cover topics such as understanding regulatory requirements, learning to design a substantial equivalence strategy, and discussing the proposed changes currently under debate.

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SALES: 317-948-4228

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Register for the Webinar

The premier notification, i.e. a 510k, is the most common pathway used to bring new medical devices to market in the US. Yet despite FDA issuing multiple guidance's since the 510k was created in 1976, 75% of 510k's are rejected i.e. via "additional information" requests and of those that are rejected, nearly 85% are rejected specifically because of substantial equivalence or the lack thereof! Simply put, no 510k should ever be rejected – and certainly not due to substantial equivalence – this is an enormous misstatement you MUST avoid. Both design and rejection result in obvious increases in time and cost to market – many of which could be prevented or avoided! One area receiving regulatory scrutiny is the substantial equivalence (SE) argument. Simply put without a strong, substantial equivalence argument, your 510k submission will not be successful. And if FDA says your device is not substantially equivalent (NSE), does it mean your device is in fact NSE? Not necessarily! But what does SE really mean and how do I know if I've said it and not what the regulation says but also what it does not say to my advantage? Using the case study approach, these questions and others will be presented in an interactive fashion.

PRESENTER

Mrs. Susan J. Liu
President
Vascular Sciences

MODERATOR

Jeff Shuren
Founder & VP QA/RA
Greenlight Guru

SPECIFICALLY THIS WEBINAR WILL COVER:

- Understand the regulatory requirements of substantial equivalence and how to use them to your advantage
- Learn to design a substantial equivalence strategy using regulatory logic and how to defend it.
- Appreciate the split, and multi-predicate strategies and how and when to use each.
- Be aware of several new FDA guidance documents and how to use them to your advantage
- Learn what to do if FDA says your device is NSE, i.e. does NSE necessarily mean NSE? what are your options?
- Discuss the proposed changes currently under debate and what the future may hold for the 510k program

Dec 6, 2018 available [here](#).

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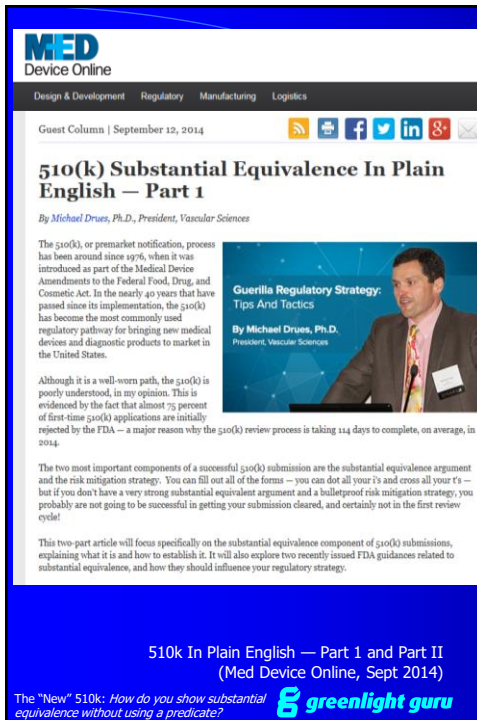
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How do you show substantial equivalence without using a predicate?



510(k) Substantial Equivalence In Plain English — Part 1

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

The 510(k), or premarket notification, process has been around since 1976, when it was introduced as part of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. In the nearly 40 years that have passed since its implementation, the 510(k) has become the most commonly used regulatory pathway for bringing new medical devices and diagnostic products to market in the United States.

Although it is a well-worn path, the 510(k) is poorly understood, in my opinion. This is evidenced by the fact that almost 75 percent of first-time 510(k) applications are initially rejected by the FDA — a major reason why the 510(k) review process is taking 114 days to complete, on average, in 2014.

The two most important components of a successful 510(k) submission are the substantial equivalence argument and the risk mitigation strategy. You can fill out all of the forms — you can dot all your i's and cross all your t's — but if you don't have a very strong substantial equivalence argument and a bulletproof risk mitigation strategy, you probably are not going to be successful in getting your submission cleared, and certainly not in the first review cycle!

This two-part article will focus specifically on the substantial equivalence component of 510(k) submissions, explaining what it is and how to establish it. It will also explore two recently issued FDA guidances related to substantial equivalence, and how they should influence your regulatory strategy.

510k In Plain English — Part I and Part II
(Med Device Online, Sept 2014)


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Read this!



510(k) Substantial Equivalence In Plain English — Part 2

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

Part 1 of this article sought to provide a better understanding of the concept of substantial equivalence in premarket notifications, more commonly known as 510(k)'s, using easy-to-understand metaphors. We also looked at recently issued CDHR draft guidance concerning different technological characteristics of a 510(k) submission. In Part 2, we move on to another piece of recent CDHR guidance, this one dealing with the controversial topic of split predicates.

The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

Since this guidance was issued on July 28, it has generated a lot of discussion in the medical device industry — not all of it positive. The controversy centers on the guidance's interpretation of split predicates. What is the split predicate strategy? Once again, let me use a metaphor that everybody can understand.

Let's think of ketchup. If ketchup was a new medical device — there was no other ketchup on the market — how could we get it onto the market under the 510(k) using the split-predicate logic? One way would be to deconstruct the ketchup. In other words, what are the components we find within the ketchup? We find tomatoes; tomatoes are on the market. We find vinegar; vinegar is also on the market. We find sugar, which is on the market. We find a variety of spices that are already on the market. If each of these components of ketchup has been previously cleared, then the combination of those components in ketchup should also be cleared. This is how the split-predicate strategy works.

I'm dating myself here, but I was one of the first to successfully argue the split-predicate rationale at CDHR about

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Simplifying Substantial Equivalence In FDA Premarket Notifications

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

The FDA's 510(k) premarket notification process is the most common pathway new medical devices take to market in the United States. And while most 510(k) submissions are eventually cleared, almost 75 percent of first-time applications are initially rejected. It's no wonder it's taking an average of 114 days for 510(k)'s to be reviewed in 2014, and that's actually an improvement over years past!

Staying current on 510(k) guidance is critical to making the process go as smoothly as possible, and the agency has issued quite a few related guidance documents in recent months. In this podcast, Michael Drues, Ph.D., author of the Med Device Online guest column series *Guerilla Regulatory Strategy*, shares some 510(k) submission strategies and explains how two recent guidances — on the topic of substantial equivalence — should influence your approach.

Audio Podcast: 510(k) — In Plain English (MED Device Online, Sept 10, 2014) (20 min)

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Simplifying Substantial Equivalence In FDA Premarket Notifications

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

The FDA's 510(k) premarket notification process is the most common pathway new medical devices take to market in the United States. And while most 510(k) submissions are eventually cleared, almost 75 percent of first-time applications are initially rejected. It's no wonder it's taking an average of 114 days for 510(k)'s to be reviewed in 2014, and that's actually an improvement over years past!

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For More Information:

- FDA Draft Guidance: *Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications [510(k)] with Different Technological Characteristics*
- FDA Draft Guidance: *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*
- Webinar: *The Premarket Notification/510(k) Submission: Using Substantial Equivalence to your Advantage*
- Contact Michael Drues via email or on LinkedIn.

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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](#).

The "New" 510k: How do you show substantial equivalence without using a predicate?

The New 510(k) Paradigm

This flowchart should only be considered in conjunction with the accompanying proposed text.

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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.

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" sp510k₂₀₁₈ substantially equivalent to a510k₁₉₉₈?

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The "New" 510k:


How do you show substantial equivalence without using a predicate?

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 \leq 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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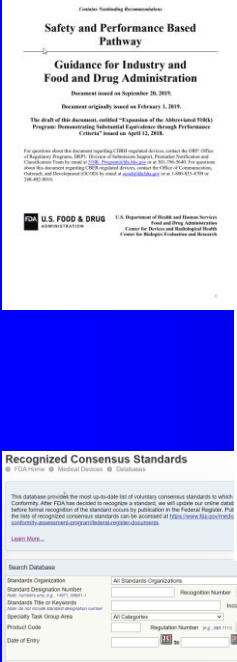
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Recognized Consensus Standards

This database provides the most up-to-date list of voluntary consensus standards to which conformity after FDA has decided to recognize is shown. We will update our online data before formal recognition of the standard occurs by publication in the Federal Register. For the full list of recognized consensus standards, please see the document at <https://www.fda.gov/oc/recognized-consensus-standards>.

Search Database

Standards Organization: All Standards Organizations
 Standard Organization Number: Registration Number:
 Standard Title or Keyword: Included in ASCA (yes) ☐
 Specialty Task Group Area: All Categories:
 Product Code: Regulatory Number: Date of Entry (dd/mm/yyyy):

Guidance: "Safety and Performance Based Pathway" (Sept, 2019) [here](#)


How to show SE to a standard?

Table 1. FDA Review of Information Provided to Demonstrate that a Device Meets Performance Criteria and Methodology Indicated in FDA Guidance for Submissions using the Safety and Performance Based Pathway


Type of Performance Criteria and Methodology FDA identified in the relevant Safety and Performance Based Pathway Guidance		Safety and Performance Based Pathway 510(k) Submission should Include
Performance Criteria	Testing Methodology	
FDA-recognized standard ¹²	FDA-recognized standard ¹²	Declaration of Conformity ¹³
FDA-established	FDA-recognized standard ¹²	Results Summary ¹⁴ and Declaration of Conformity ¹³
FDA-established	FDA-recommended or specified	Results Summary ¹⁴ and Testing Protocol ¹⁵
FDA-established	None specified/recommended or alternative to FDA-specified methodology used	Complete Test Report ¹⁶

Basic Regulatory Due-Diligence:
Check recognized consensus standards data, guidance document database, product code database, etc.

The "New" 510k: How do you show substantial equivalence without using a predicate?

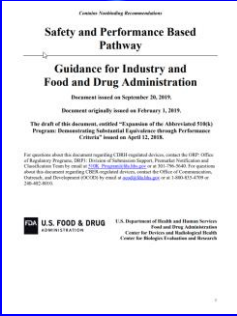


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Compare to other 510k's...

Anything
new/different
here?

Nope!


Guidance: "Safety and Performance Based Pathway" (Sept, 2019) [here](#)

What goes into a sp510k?


Appendix. Submission Recommendations for a 510(k) in the Safety and Performance Based Pathway

1. Medical Device User Fee Cover Sheet (Form FDA 3601)
2. CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)
3. 510(k) Cover Letter
4. Indications for Use Statement (Form FDA 3881)
5. 510(k) Summary or 510(k) Statement
6. Truthful and Accuracy Statement
7. Class III Summary and Certification
8. Financial Certification and/or Disclosure Statement (Forms FDA 3454 and 3455)
9. Declarations of Conformity and Summary Reports
10. Device Description
11. Executive Summary/Predicate Comparison
12. Substantial Equivalence Discussion
13. Proposed Labeling
14. Sterilization and Shelf Life
15. Biocompatibility
16. Software
17. Electromagnetic Compatibility and Electrical Safety
18. Performance Testing – Bench
19. Performance Testing – Animal
20. Performance Testing – Clinical
21. Other

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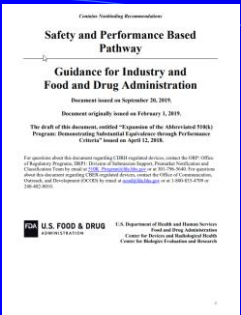
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How do you show substantial equivalence without using a predicate?



Guidance: "Safety and Performance Based Pathway" (Sept, 2019) [here](#)

Do we need a predicate for a sp510k?

Short answer: *Yes and No*

12. Substantial Equivalence Discussion

In the substantial equivalence section, ***we continue to recommend that you identify the predicate*** by providing its trade name, model number, name of the 510(k) submitter/holder, and 510(k) number, if available.

- Why?



We recommend that you ***provide a comparison between your device and the predicate in terms of indications for use and technology.***

- Isn't that true with ***all 510k's***?

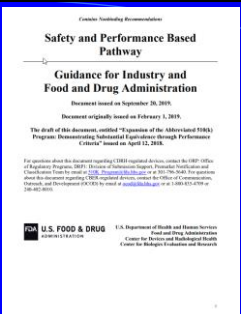
If you choose to use the Safety and Performance Based Pathway, ***we do not expect you to provide direct comparison testing against a legally marketed device for performance specifications.*** Any testing you conduct in accordance with standards or guidance should be as described in sections 9, 12, and 13-20, as applicable.

- Doesn't that sound like the ***a510k***?

So what if anything is really "new" here?

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Guidance: "Safety and Performance Based Pathway" (Sept, 2019) [here](#)

Do we need a predicate for a sp510k?



Short answer: *Yes and No*

13 - 20. Proposed Labeling, Sterilization and Shelf Life, Biocompatibility, Software, Electromagnetic Compatibility and Electrical Safety, and Performance Testing – Bench, Animal, and Clinical, as applicable

We continue to recommend that ***submitters of 510(k)s through the Safety and Performance Based Pathway provide the information as you would in a traditional 510(k) for the sections on Proposed Labeling, Sterilization and Shelf Life, Biocompatibility, Software, Electromagnetic Compatibility and Electrical Safety, and Performance Testing, except that FDA would not expect your information to describe direct comparison testing against the predicate device.*** Instead, FDA recommends that you include a Declaration of Conformity, results summary, testing protocols and/or complete test report, as applicable, demonstrating the new device meets the performance criteria using appropriate testing methods.

See FDA Guidance: *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices* [here](#).

So just like in all 510k's, we still need a predicate... but for different reasons!

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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
Pancreatic Supplement	\$281,143	\$70,285
Real-Time Supplement	\$26,340	\$6,500
BLA Efficacy Supplement	\$374,858	\$93,714
30-Day Notice	\$10,000	\$2,500
Annual Fee for Periodic Reporting on a Class II device (PMAs, PDs, and PMRs)	\$13,120	\$3,280

† **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:

How do you show substantial equivalence without using a predicate?

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:

How do you show substantial equivalence without using a predicate?

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
- The new device meets all the FDA-identified performance criteria.

– DUH!

If any of the above factors are not met, the submitter must use the 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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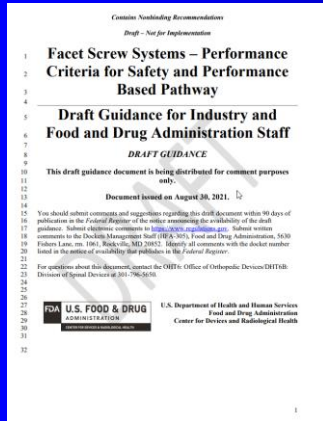
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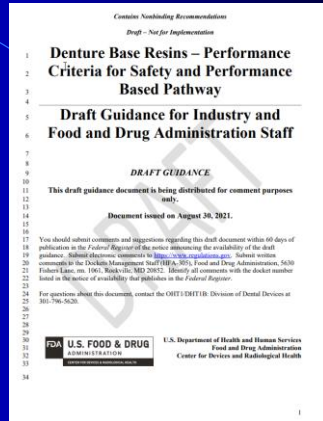
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Where are we headed with this?



CDRH Guidance (Aug, 2021) [here](#)



CDRH Guidance (Aug, 2021) [here](#)

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

How long will that take? What will it cost?

The "New" 510k: How do you show substantial equivalence without using a predicate?



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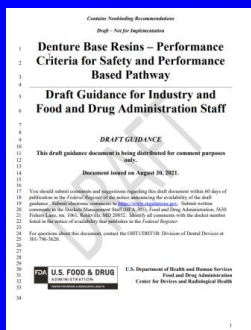
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What's in these guidance's?



CDRH Guidance (Aug, 2021) [here](#)

- 168 **Mechanical Bench Testing**
- 169
- 170 1. **Test name:** Ultimate flexural strength
- 171 **Methodology:** ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers
- 172 **Performance Criteria:**
- 173 **Types 1, 3, 4, and 5 polymers:** $\geq 65 \text{ MPa}$
- 174 **Type 2 polymers:** $\geq 60 \text{ MPa}$
- 175 **Performance Criteria Source:** ISO 20795-1 (2013) Dentistry – Base polymers – Part 1:
- 176 **Denture base polymers**
- 177 **Submission Information:** DoC
- 178
- 179 2. **Test name:** Flexural modulus
- 180 **Methodology:** ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers
- 181 **Performance Criteria:**
- 182 **Types 1, 3, 4, and 5 polymers:** $\geq 2000 \text{ MPa}$
- 183 **Type 2 polymers:** $\geq 1500 \text{ MPa}$
- 184 **Performance Criteria Source:** ISO 20795-1 (2013) Dentistry – Base polymers – Part 1:
- 185 **Denture base polymers**
- 186 **Submission Information:** DoC
- 187
- 188 3. **Test name:** Stress intensity factor
- 189 **Methodology:** ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers
- 190 **Performance Criteria:** Types 1-5 polymers: $\geq 1.9 \text{ MPa} \cdot \text{m}^{1/2}$
- 191 **Performance Criteria Source:** ISO 20795-1 (2013) Dentistry – Base polymers – Part 1:
- 192 **Denture base polymers**
- 193 **Submission Information:** DoC
- 194
- 195 4. **Test name:** Fracture work
- 196 **Methodology:** ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers
- 197 **Performance Criteria:** Types 1-5 polymers: $\geq 900 \text{ J/m}^2$
- 198 **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!

The "New" 510k: How do you show substantial equivalence without using a predicate?



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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!* 😊

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The "New" 510k:


How do you show substantial equivalence without using a predicate?

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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How do you show substantial equivalence without using a predicate?



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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**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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The "New" 510k:

How do you show substantial equivalence without using a predicate?

IF YOU CAN THINK IT, WE CAN DO IT.

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

Albert Einstein

Logic

Imagination

A B

A B

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

Albert Einstein

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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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