

Refuse to Accept (RTA) & Additional Information Requests (AIR):

How to Avoid Problems with Your Medical Device Submission?

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 (March 23, 2023)

www.greenlight.guru/webinar/refuse-to-accept-additional-information-requests-avoid-problems-medical-device-submission

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

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Refuse to Accept (RTA) and Additional Information Requests (AIR):

Why do so many medical device submissions have such avoidable problems?

presented by: **Michael Drues, Ph.D.**

Despite FDA publishing multiple *Refuse-To-Accept* (RTA) guidance documents for all major medical device submission types including the 510k, de novo and PMA, ***more than two-thirds of all medical device submissions result in an Additional Information Request (AIR) and/or are rejected upon administrative review i.e., Refuse-to-Accept*** (see MDUFA statistics [here](#)). Regrettably, ***when a submission is rejected on administrative review, it is solely the fault of the company not the FDA!***

The purpose of this webinar is to review the available RTA checklists and most importantly to learn to design a submission that will pass administrative review and avoid receiving an Additional Information Request (AIR) or Refuse-to-Accept (RTA) determination which will undoubtedly lead to delays to market!

In his signature style, Dr. Michael Drues will use actual devices as case studies to discuss:

- The FDA review process: administrative review vs. substantive/scientific review
- Actual (not hypothetical) examples of AIRs and RTAs from real medical device submissions
- Practical and actionable advice on how to avoid RTA determinations
- Advice on using electronic tools to minimize RTA determinations
- Strategies on how to deal with AIRs and RTAs should you receive one

Simply put: whether we need them or not, FDA has published these RTA checklists... we might as well use them to our advantage!

About the Presenter



[Michael Drues](#), Ph.D., is a regulatory strategy consultant specializing in designing novel regulatory strategies to bring new and innovative medical products to market and in developing effective communication strategies between companies and regulatory agencies to minimize time to market and avoid delays.

Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University. He works with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. He also works on a regular basis for the U.S. Food and Drug Administration, Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services and other regulatory and governmental agencies around the world.

Dr. Drues is an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and regulatory affairs. He conducts seminars and short courses for medical device, pharmaceutical and biotechnology companies, the FDA, Health Canada, the US and European Patent Offices, CMS and other regulatory and governmental agencies around the world.

Finally, Dr. Drues is an Adjunct Professor of Regulatory Affairs, Medicine and Biomedical Engineering at several universities and medical schools. He regularly teaches graduate courses in Regulatory Affairs and Clinical Trials, Product Development, Combination Products and Pathophysiology.

For additional information, contact Dr. Drues directly at (508) 887-9486, e-mail mdrues@vascularsci.com or via LinkedIn at www.linkedin.com/in/michaeldrues.

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- Director of RA/QA

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★★★★★

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★★★★★

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Refuse to Accept (RTA) & Additional Information Requests (AIR):

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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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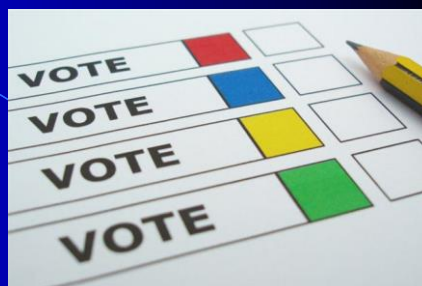


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Before we begin...

Polling Questions



I received an AIR following an FDA submission? [y/n]

I received an RTA or MDL following an FDA submission? [y/n]

I was surprised to receive an AIR, RTA or MDL? [y/n]

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

- ✓ FDA review process: administrative review vs. substantive/scientific review
- ✓ Actual (not hypothetical) examples of AIRs and RTAs from real medical device submissions
- ✓ Practical and actionable advice on how to avoid RTA determinations
- ✓ Advice on using electronic tools to minimize RTA determinations
- ✓ Strategies on how to deal with AIRs and RTAs should you receive one
- ✓ Case studies and bonus questions... time permitting
- ✓ Lots more tips and tricks... time permitting!
- ✓ Final thoughts...

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Can your submission be rejected



Absolutely, in fact... most are!

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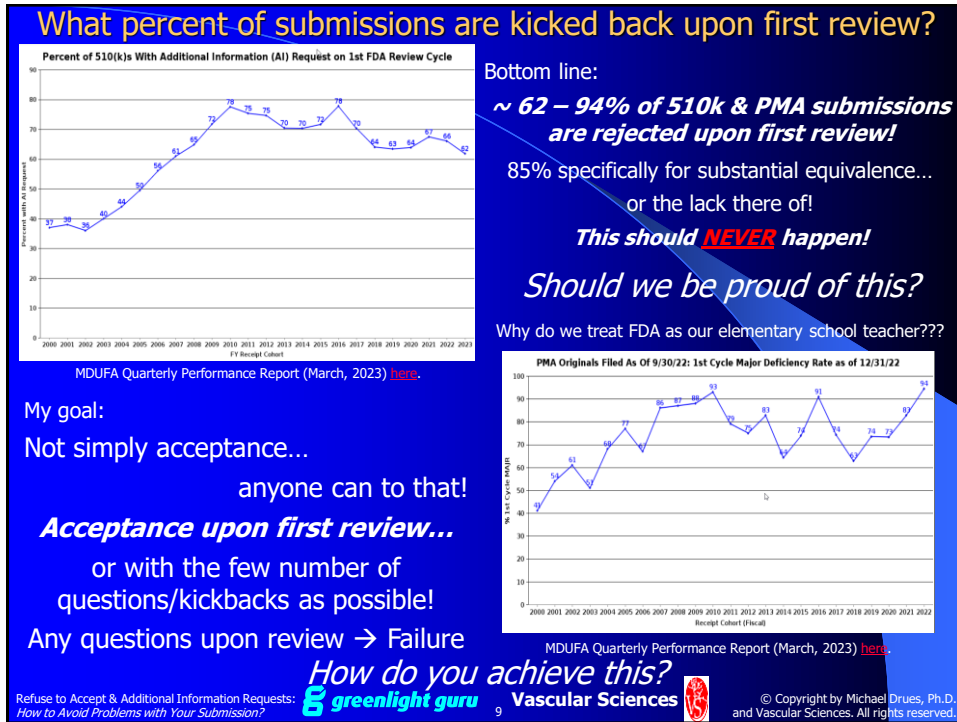
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Mikes Mantra

**Guerilla Regulatory Strategy:
Tips And Tactics**

**By Michael Druess, Ph.D.
President, Vascular Sciences**

Repeat after me:

Tell don't ask...

lead don't follow...

learn don't bash!

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Don't believe me... do your own fact checking!

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MDUFA Reports

The FDA provides annual and quarterly reports on its progress towards meeting performance goals and commitments set under MDUFMA to its stakeholders and Congress.

The FDA also provides an annual financial report to Congress to help ensure transparency and accountability of its use of the additional resources provided by MDUFMA.

MDUFA Annual Reports

- MDUFA Performance Reports
- MDUFA Financial Reports

MDUFA Quarterly Performance Reports

Each report includes the agenda for the quarterly meeting and the quarterly performance data.

MDUFA V

- March 1, 2023 MDUFA V Performance Report

Content current as of: 03/02/2023

Regulated Product(s): Medical Devices

Updated quarterly – our user fees hard at work! 😊

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Are we making progress?

Apparently not...

1994 (original guidance)

↓

2012 (updated guidance)

↓

2015 (yet another "updated" guidance)

↓

2022 (yet another "updated" guidance)

Note: at least no "final" guidance

And yet...

"As of September 2013, ~60% of all newly filed 510(k)s were refused under the RTA."

FDA News, Falls Church, VA Sept. 30, 2013

Refuse to Accept Policy for 510(k)s (December, 2012 available [here](#))

Contains Nonbinding Recommendations

Refuse to Accept Policy for 510(k)s

Guidance for Industry and Food and Drug Administration Staff

Document issued on: August 4, 2015

As of October 1, 2015, this document supersedes "Food and Drug Administration's Refuse to Accept Policy for 510(k)s," dated December 31, 2012, "Premarket Notification (510(k)) Refuse to Accept Policy," dated June 30, 1993, and "510(k) Refuse to Accept Procedures (K04-1) blue book memo", dated May 20, 1994.

For questions regarding this document, contact the 510(k) Staff at 301-796-5640. For questions regarding submissions to the Center for Biologics Evaluation and Research (CBER), contact CBER's Office of Communication, Outreach and Development at 1-800-535-4709 or 240-402-8010.

Center for Devices and Radiological Health (CDRH)

Center for Biologics Evaluation and Research (CBER)

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

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Checklist vs. Refuse to Accept



Use this to avoid RTA's...
but do we (should we?) really need it?

Organizational Elements		
Failure to include these items alone generally should not result in an RTA designation		
	Yes	No
a. Submission contains Table of Contents	<input type="checkbox"/>	<input type="checkbox"/>
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	<input type="checkbox"/>	<input type="checkbox"/>
c. All pages of the submission are numbered <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i>	<input type="checkbox"/>	<input type="checkbox"/>
d. Type of 510(k) is identified—traditional, abbreviated, or special <i>If type of 510(k) is not designated, review as a traditional</i>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:		

Refuse to Accept Policy for 510(k)s (April, 2022 available [here](#))

Contains Nonbinding Recommendations

Refuse to Accept Policy for 510(k)s

Guidance for Industry and Food and Drug Administration Staff

Document issued on: April 21, 2022.
Document originally issued on May 20, 1994.

This document supersedes "Refuse to Accept Policy for 510(k)s" issued September 13, 2019.

For questions about this document regarding CDRL-regulated devices, contact ORP: Office of Regulatory Programs, DRP: Division of Submission Support, Premarket Notification and Classification Team by email at 510K_Program@fda.hhs.gov or at 301-796-5640.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) by email at ocod@fda.hhs.gov or at 800-835-4709 or 240-402-8010.

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Are we making progress?



Insanity:
doing the same thing
over and over again
and expecting
different results.
- Albert Einstein

Better Definition



The definition of
insanity is
repeating the same
mistakes
over and over
again and expecting
different
results.
- Albert Einstein

Or put another way...

Practice does not make perfect...

perfect practice makes perfect!

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Use the RTA checklist to your advantage!

The image shows a stack of 'Acceptance Checklist' forms for Special 510(k)s. The top form is titled 'Contains Nonbinding Recommendations' and 'Acceptance Checklist for Special 510(k)s'. It includes a section for 'Special 510(k) Criteria' with four criteria to be evaluated: 1. Is the submission submitted to a newly marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device? 2. Is the submission for use of the proposed device unchanged from the legally marketed device (predicate)? 3. Does the submission include only summary-level information (i.e., NO test report with performance data)? 4. Does the submission include only summary-level information (i.e., NO test report with performance data)? The form also includes a section for 'Does the submission meet all 4 criteria above?' and a 'Comments' section.

RTA guidance includes checklists for traditional (24 pages), special (10 pages) and abbreviated (26 pages) 510k...

What does that say?

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Meet the family...

This document provides guidance for industry and FDA staff regarding the 'Refuse to Accept Policy for 510(k)s'. It was issued on April 21, 2022, and originally issued on May 26, 1994. The document supersedes the 'Refuse to Accept Policy for 510(k)s' issued September 13, 2019. For questions about this document regarding CDRE-regulated devices, contact the Office of Regulatory Programs (ORP), Division of Submission Support, Premarket Notification and Classification (PNC) by email at 1218_Pnc@fda.hhs.gov or at 301-796-5640. For questions about this document regarding CDRE-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) by email at ocod@fda.hhs.gov or at 800-835-4709 or 240-402-8010.

Refuse to Accept Policy for 510(k)s
(April, 2022 available [here](#))

This document provides guidance for industry and FDA staff regarding the 'Acceptance Review for De Novo Classification Requests'. It was issued on October 5, 2021, and originally issued on September 9, 2019. For questions about this document regarding CDRE-regulated devices, contact the Division of Industry and Consumer Education (DICE) at 1-800-638-2842, 301-796-7108, or DICE@fda.hhs.gov. For questions about this document regarding CDRE-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

Guidance: Acceptance Review for De Novo
Classification Requests (Oct, 2021) [here](#)

This document provides guidance for industry and FDA staff regarding the 'Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)'. It was issued on December 16, 2019, and originally issued on May 1, 2003. This document supersedes the 'Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)' dated February 21, 2019. For questions about this document regarding CDRE-regulated devices, contact the Office of Regulatory Programs (ORP), Division of Submission Support, Premarket Notification and Classification (PNC) by email at 1218_Pnc@fda.hhs.gov or at 301-796-5640. For questions about this document regarding CDRE-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

Acceptance and Filing Reviews for Premarket
Approval Applications (PMAs) (Dec, 2019) [here](#)

If you get an AIR or RTA, what's your excuse?

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Additional Resources

Free Live Webinar by **greenlight guru** + **VASCULAR SCIENCES**

ARE YOU SURE YOU KNOW THE BEST REGULATORY PATHWAY FOR YOUR NEW MEDICAL DEVICE?

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April 2nd @ 1:00p ET / 10:00a PT

Presenter



MICHAEL DRUES, PH.D.
President at Vascular Sciences

Moderator



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

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

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Would you like a demo of Greenlight Guru's software?*

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The premarket notification, a.k.a. the 510K, is the most common pathway used to bring new medical devices to market in the US. Yet despite FDA issuing multiple guidances since the 510K was created in 1976, 75% of 510Ks are rejected for "insufficient information" requests and of those that are rejected, nearly 85% are rejected specifically because of substantial equivalence or the lack thereof.

Simply put, no 510Ks should ever be rejected – and certainly not due to substantial equivalence – this is an amateur mistake! (see MORA 1/1/13)

Such delays and rejections result in obvious increases in time and cost to market – many of which could be minimized or avoided!

One area requiring 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 know do I use not just 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.

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
- Appropriate the safe and well-investigate 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

PRESENTER



Michael Drues, Ph.D.
President Vascular Sciences

MODERATOR



Jon Speer
Founder & VP QA/RA, Greenlight Guru

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

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FREE ON-DEMAND WEBINAR

ADVANCED STRATEGIES AND TACTICS FOR USING THE DE NOVO PATHWAY

Advanced Strategies and Tactics for Using the De Novo Pathway
presented by:
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President, Vascular Sciences, Grafton, Massachusetts
Adjunct Professor of Regulatory Science, Medicine, and Biomedical Engineering
GreenLight.Guru Webinar (December 7, 2017)
<http://blog.greenlight.guru/topics/mike-drues>
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Join me on LinkedIn at www.linkedin.com/in/michaeldrues

Webinar + Handout (December, 2017) available [here](#)

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THE PRE-MARKET APPROVAL (PMA): IS IT REALLY AS BAD AS SO MANY THINK?

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Presenter
MICHAEL DRUES PH.D.
President
Vascular Sciences

Moderator
JON SPEER
Founder & VP QA/RA
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Comparison by Page Count?

Refuse to Accept Policy for 510(k)s	Acceptance Review for De Novo Classification Requests	Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)
<p><i>Contains Nonbinding Recommendations</i></p> <p>Refuse to Accept Policy for 510(k)s</p> <p>Guidance for Industry and Food and Drug Administration Staff</p> <p>Document issued on: April 21, 2022.</p> <p>Document originally issued on May 28, 1994.</p> <p>This document supersedes "Refuse to Accept Policy for 510(k)s" issued September 12, 2019.</p> <p>For questions about this document regarding CDREI-regulated devices, contact ORP, Office of Regulatory Programs, DFT, Division of Submission Support, Premarket Notifications and Classification Team by email at 1-800-835-4709 or orpl@fda.hhs.gov or at 301-796-5640.</p> <p>For questions about this document regarding CDREI-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) by email at ocod@fda.hhs.gov or at 800-835-4709 or 240-402-8010.</p> <p>FDA U.S. FOOD & DRUG ADMINISTRATION</p> <p>U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health Center for Biologics Evaluation and Research</p>	<p><i>Contains Nonbinding Recommendations</i></p> <p>Acceptance Review for De Novo Classification Requests</p> <p>Guidance for Industry and Food and Drug Administration Staff</p> <p>Document issued on October 5, 2021.</p> <p>Document originally issued on September 9, 2019.</p> <p>For questions about this document regarding CDREI-regulated devices, contact the Division of Industry and Consumer Education (DICE) at 1-800-635-2641, 800-796-7396 or dice@fda.hhs.gov.</p> <p>For questions about this document regarding CDREI-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.</p> <p>FDA U.S. FOOD & DRUG ADMINISTRATION</p> <p>U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health Center for Biologics Evaluation and Research</p> <p>ORP Control No. 9910-0844</p> <p>Current expiration date available at https://www.access.gpo.gov.</p> <p>See additional FRA statement in Section VII of this guidance.</p>	<p><i>Contains Nonbinding Recommendations</i></p> <p>Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)</p> <p>Guidance for Industry and Food and Drug Administration Staff</p> <p>Document issued on December 16, 2019.</p> <p>Document originally issued on May 1, 2003.</p> <p>This document supersedes Acceptance and Filing Reviews for Premarket Approval Applications (PMAs), dated February 21, 2019.</p> <p>For questions about this document regarding CDREI-regulated devices, contact the Office of Regulatory Programs at 301-796-5640. For questions about this document regarding CDREI-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.</p> <p>FDA U.S. FOOD & DRUG ADMINISTRATION</p> <p>U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health Center for Biologics Evaluation and Research</p>
Refuse to Accept Policy for 510(k)s (April, 2022 available here)	Guidance: Acceptance Review for De Novo Classification Requests (Oct, 2021) here	Acceptance and Filing Reviews for Premarket Approval Applications (PMAs) (Dec, 2019) here
102 pages	35 pages	36 pages
What does that say?		
i.e., Novel (de Novo) and/or Riskier Devices (PMA) << Me-too (510k) Devices?		
Does that make sense?		
Refuse to Accept & Additional Information Requests: How to Avoid Problems with Your Submission?	greenlight guru	Vascular Sciences

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Are they substantially equivalent?



*We must always look for similarities...
even when no similarities appear to exist!*

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Refuse to Accept (RTA) & Additional Information Requests (AIR):

How to Avoid Problems with Your Medical Device Submission?

Are these substantially equivalent?

Refuse to Accept Policy for 510(k)s

Guidance for Industry and Food and Drug Administration Staff

Document issued on: April 21, 2022.
Document originally issued on May 20, 1994.
This document supersedes "Refuse to Accept Policy for 510(k)s" issued September 13, 2019.

For questions about this document regarding CDRL-regulated devices, contact ORP, Office of Regulatory Programs, DRP, Division of Submission Support, Premarket Notification and Classification Team by email at 210R_Program@fda.hhs.gov or at 301-796-5640.

For questions about this document regarding CDRL-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) by email at ocod@fda.hhs.gov or at 800-835-4709 or 240-402-3010.

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

VS.

Refuse to File: NDA and BLA Submissions to CDER

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 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. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.


For questions regarding this draft document, contact Amalia Homayra at 301-796-0700.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)


December 2017
Procedural

Refusal to file (RTF) is FDA's formal decision to deny review of an NDA or BLA due to application deficiencies.

Refuse to File: NDA and BLA Submissions to CDER Guidance (Dec, 2017 [here](#))

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What is missing in the picture?


What RTA guidance's do we not have?

Is there an RTA guidance for pre-sub?

Nope!

Should there be?

But there are many resources available...

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Mike's Pre-Sub Resources

2-hr Seminar: **Conducting Effective FDA Pre-Submission Meetings** (Med Device Tech Exchange, April, 2018) [here](#).

Podcast: **How to Properly Use the FDA Pre-Submission Process and Why It's So Important** (August, 2016) [here](#).

Column: **How To Make The Most Of Your Pre-Sub Interactions with FDA** (Med Dev Online, Feb, 2015) [here](#).

Column: **Communicating With FDA: How (And When) To Get It Right** (Med Dev Online, June, 2015) [here](#).

Editorial: **3 Tips To Vastly Improve Your FDA Communication Strategy** (MDDI, May, 2014) [here](#).


Podcast: **How To Make The Most Of Your Pre-Submission Interactions With FDA** [here](#).

Podcast: **How to Properly Use the FDA Pre-Submission Process and Why It's So Important** [here](#).



Podcast: **When And How To Interact With The FDA** (MED Device Online, March, 2015) [here](#).

Webinar: **Communication With FDA: What Do We Say and How Do We Say It?** (GWU, Jan, 2016) [here](#).

Should you be interested... ☺


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Why did FDA reject 58% of all 510k submissions in 2013

Refuse-to-Accept (RTA) Policy

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How to Avoid Problems with Your Medical Device Submission?

Don't blame FDA... learn from others mistakes!

In 2013,

2,965 510k's received = 1,197 Accepted + 1,715 RTA [+ 53 MIA?]

Percent of Submissions Not Accepted under RTA = 58%

Why?

Some Reported Reasons for Refusal

- ✓ Failure to state whether a condom was patient contacting

Recommendation: *Don't assume FDA understands your device!*

- ✓ Failure to comply with a *draft* guidance document

Recommendation: *Draft vs. Final doesn't matter - you don't have to comply but you must justify!*

- ✓ Failure to indicate vinyl glove does not contain software or met electrical safety requirements

Recommendation: *Don't leave something out because you think it doesn't apply!*

- ✓ Typos, misprints, duplicate pages, etc.

Recommendation: *Do I really need to say... proof-read! AND don't ask FDA to be your β -tester!*

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How to Avoid Problems with Your Submission?



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How to avoid unnecessary delays?



Most delays are avoidable!

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Refuse to Accept (RTA) & Additional Information Requests (AIR): *How to Avoid Problems with Your Medical Device Submission?*

How to avoid unnecessary delays?

Most delays are avoidable!

What's the review process?

Administrative Review

↓

Scientific Review

Remember,

Never OMIT a section!

and

Always use the current forms!

Keeps the bureaucrats happy! ☺

Call **DICE?**

CDRH Premarket Review Submission Cover Sheet (FDA 3514) (June, 2023) [here](#) (online [here](#))

Refuse to Accept & Additional Information Requests: [How to Avoid Problems with Your Submission?](#)

The screenshot shows the FDA's Medical Devices website. The top navigation bar includes links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco. The main content area is titled 'Medical Devices' and features a sidebar with links to various resources, including 'Device Advice: Comprehensive Regulatory Assistance', 'How to Market Your Device', 'Premarket Submissions', and 'Premarket Notification (510k)'. The main text area is titled 'Content of a 510(k)' and provides detailed information about the submission process, including the introduction, table of contents, and specific requirements for the submission. The URL <https://www.fda.gov/medical-devices/premarket-notification-510k/content-510k> is displayed at the bottom of the screenshot.

<https://www.fda.gov/medical-devices/premarket-notification-510k/content-510k>

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How much detail must I provide in my submission

There is no answer... sorry!

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Refuse to Accept (RTA) & Additional Information Requests (AIR): How to Avoid Problems with Your Medical Device Submission?

What kind of submission? How much detail?

Question: **What kind of submission do I need for a class I device? How in depth?**

In a nut-shell:

- if Class I Exempt → no 510k submission is required (registration is still required in most cases)
- if Class I non-exempt → 510k is required

Note:

General submission requirements are no different for Class I vs. Class II however...

Class II 510k is going to require more 'detail' than class I due to higher risk, etc.

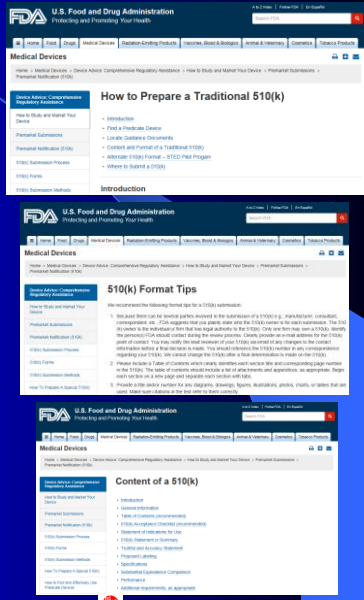
Also, Design Controls apply to some Class I devices and all class II devices.



Here are a few resources you might find useful:

- How to Prepare a Traditional 510(k) available [here](#).
- 510(k) Format Tips available [here](#).
- Content of a 510(k) available [here](#).

How much detail? My recommendation:

Put yourself in the shoes of the reviewer!



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Don't be penny wise and pound foolish!

Look how easy a 510k can be! →

If you needed surgery...

Would you want your surgeon following a template?

Even for simple devices...

Is it worth it?

Remember...

Most problems are predictable and preventable


and

Usually it costs more time and money to clean up other people's messes!

Screenshot (July, 2015) available [here](#).

FDA 510(k) Templates

510(k) Templates Are Customizable for Traditional, Abbreviated, and Special 510(k)s and Are Made Compliant with the e-Copy and RTA Policy Requirements

510(k) Preparation Made EZ! – USE TEMPLATES!!!

510(k) Templates

1. For Traditional, Abbreviated and Special 510(k)s
2. Documents in Word
3. Prepared Section by Section
4. Customizable
5. Cover Letter Included
6. eCopy Ready Format
7. RTA Items-Made Easy to Address
8. Support Available While Using the Template Forms
9. **YOU SAVE TIME and EFFORTS!!!**

\$119-149

➤ **Delivered Within 24 Hours of Purchase**

Customizable 510(k) Templates Are Available for Three 510(k) Types (Traditional, Abbreviated, and Special)

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Refuse to Accept (RTA) & Additional Information Requests (AIR): *How to Avoid Problems with Your Medical Device Submission?*

Can I (should I) use e-tools to mitigate AIR and RTA risk



Short answer: *yes and no*
i.e., recognize their strengths and limitations

Suggestion: Think



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What is the eSTAR Pilot Program and How Will it Improve FDA's 510(k) Review Process?

Written by: **NICK TIPPMANN**
March 12, 2020



JON SPEER
Founder & VP of QA/RA
Greenlight Guru

MICHAEL DRUES, PH.D.
President
Vascular Sciences



GLOBAL MEDICAL DEVICE PODCAST
Powered by **greenlight guru**

The FDA announced another new pilot program to improve the consistency and efficiency of its 510(k) review process. It's called, eSTAR, or electronic Submission Template And Resource.

www.greenlight.guru/blog/what-is-estar-pilot-program-and-how-will-it-improve-fda-510k-review-process

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How to Avoid Problems with Your Medical Device Submission?

How about some




 Additional Information Request: *Usability* [510k AIR Hold Letter](#)

 Additional Information Request: *Biocompatibility*

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Free Live Webinar by  **greenlight guru** +  **VASCULAR SCIENCES**


**USABILITY TESTING:
WHY CAN'T WE GET
IT RIGHT?**

REGISTER NOW → September 22nd @
1:00p ET / 10:00a PT



Presenter

 **MIKE DRUES**
President,
Vascular Sciences

Moderator

 **JON SPEER**
Founder,
Greenlight Guru

<https://www.greenlight.guru/webinar/usability-testing>

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How to Avoid Problems with Your Medical Device Submission?

If Time Permits...




BONUS QUESTIONS

AND ANSWERS BELOW

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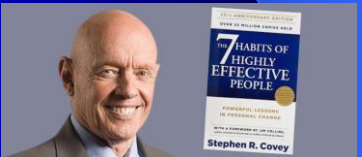
How do I deal with AIRs and RTAs should I receive one





Short answer: apply

Specifically habit #5:

*Seek first to understand...
then seek to be understood.*



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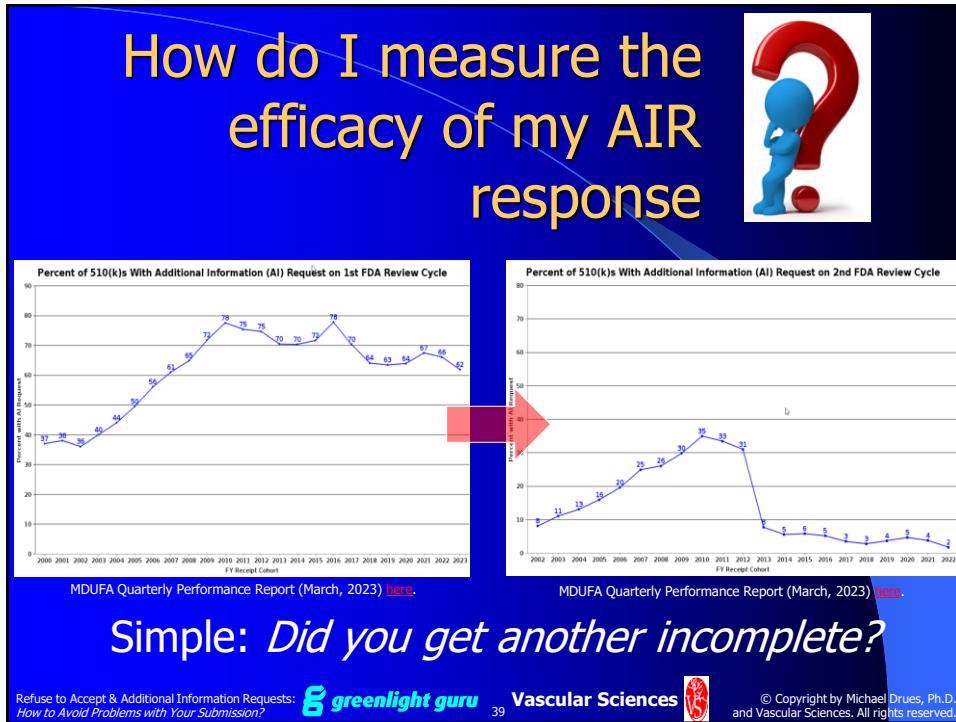
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What's the





- ✓ Put yourself in the shoes of the reviewer
- ✓ Don't treat the FDA as your β -tester
- ✓ Remember

If you get an AIR, you got an incomplete!

If you get an RTA or MDL, you got an F!

If you don't get an AIR, RTA or MDL, does that mean you got an "A" – *nope!*

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Here's what we talked about...

- ✓ FDA review process: administrative review vs. substantive/scientific review
- ✓ Actual (not hypothetical) examples of AIRs and RTAs from real medical device submissions
- ✓ Practical and actionable advice on how to avoid RTA determinations
- ✓ Advice on using electronic tools to minimize RTA determinations
- ✓ Strategies on how to deal with AIRs and RTAs should you receive one
- ✓ Case studies and bonus questions... time permitting
- ✓ Lots more tips and tricks... time permitting!
- ✓ Final thoughts...

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What is the "right" amount of regulation?



There's nothing magic about regulations, too much is bad, too little is bad.
— Hillary Clinton —

Mike's Mantra (one of many):

If the regulation makes sense... we shouldn't need it!

If the regulation doesn't make sense... we shouldn't have it!

Remember...

The surgery went perfectly but the patient died anyway!

We followed the regulations perfectly but the patient died anyway!

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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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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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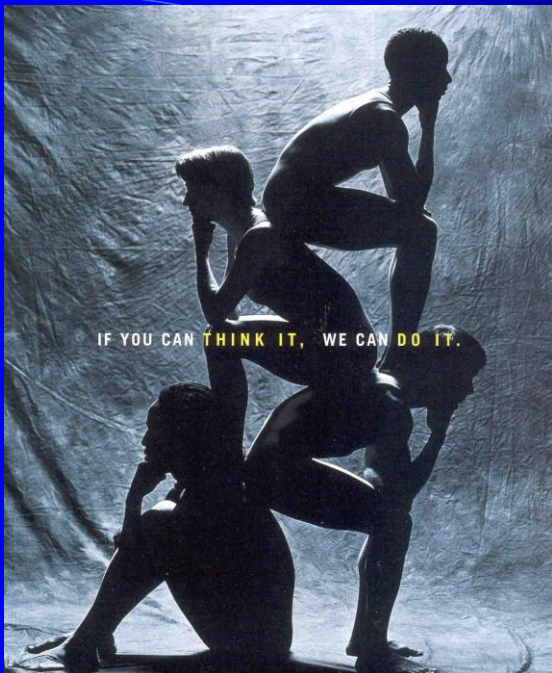
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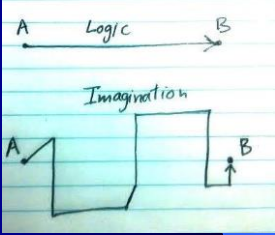
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IF YOU CAN THINK IT, WE CAN DO IT.

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



A Logic B

Imagination

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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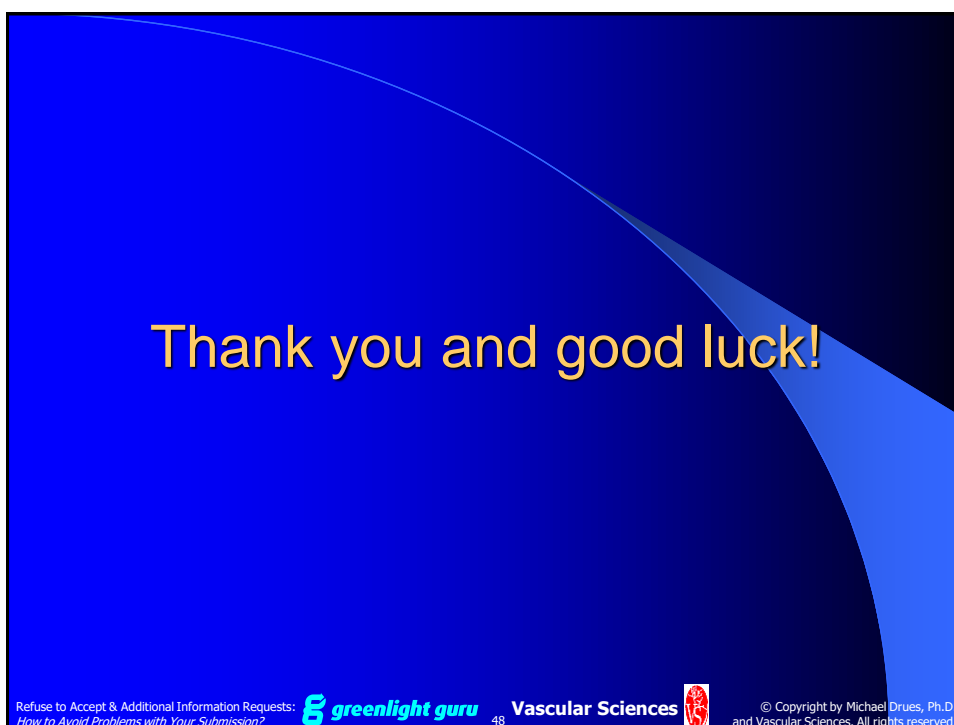
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How to Avoid Problems with Your Medical Device Submission?



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GreenLight.Guru Webinar (March 23, 2023)

www.greenlight.guru/webinar/refuse-to-accept-additional-information-requests-avoid-problems-medical-device-submission

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