

How can Medical Device Companies use the Emergency Use Authorization (EUA) to Address the COVID-19 Pandemic?

Presented by:

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and

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Cornell University Graduate Dept. of Biomedical Engineering

GreenLight.Guru Webinar (April 22, 2020)

<https://www.greenlight.guru/webinar/covid-19-emergency-use-authorization-eua-medical-device-companies>

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How can Medical Device Companies use the Emergency Use Authorization (EUA) to Address the COVID-19 Pandemic?

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

From facemasks to ventilators, the medical device industry has the potential to lead the response to the COVID-19 pandemic. For companies developing new devices, or for companies making modifications to existing devices, how can companies get these devices to market quickly to benefit the growing number of COVID-19 patients who need them?

The Emergency Use Authorization (EUA) is one regulatory mechanism some have used successfully to bring devices to market quickly. But is the EUA the only option? What are the requirements of the EUA and how do we use it? Does the EUA mean a lower regulatory burden, i.e., less testing and faster to market compared to other pathways?

In an attempt to get devices to patients who need them, FDA is “relaxing the rules” for more devices including infusion pumps, clinical thermometers, extracorporeal membrane oxygenation and cardiopulmonary bypass devices, and remote ophthalmic assessment and monitoring devices. As the current health emergency continues, more devices will likely be added to this list.

But it’s not enough for companies and FDA to respond quickly... we must also respond correctly. What’s worse: ***not having enough ventilators OR having ventilators that don’t work?*** Regrettably, we are already seeing cases of this happening. There are reports of ***hundreds to thousands of ventilators that don’t work!*** How do we meet the regulatory and quality requirements that ensure devices are safe and effective while at the same time making sure these devices are available quickly to the increasing number of people who need them?

FDA has now issued nearly as many warning letters to companies marketing products for coronavirus ***as the number of EUA’s issued thus far!*** Why is this important? Simple. The more warning letters, the more scrutiny FDA will apply to future EUA applications meaning more supportive evidence will be required and the longer the time to review.

In this workshop, we will explore the Emergency Use Authorization— specifically in the context of COVID-19 — and how device companies can use it. Using the case study approach, these questions and others will be presented in an interactive fashion including:

- What is the Emergency Use Authorization (EUA) and how do we use it?
- Which devices qualify for the EUA and which do not? Does it matter if it’s an existing device or a new device?
- What are the regulatory requirements for the EUA and what’s the process for applying?
- What are the testing requirements for the EUA and how do we find them? How much evidence is required for an EUA?
- If the EUA is not applicable, what other options exist?
- What are the quality and validation requirements for COVID-19 related devices?
- How should we modify our QMS for devices used during the COVID-19 crisis?
- How do we handle devices coming back from the field, i.e., devices recalled from hospitals?
- What happens to devices with EUA after this public health crisis is over?
- How can a company get their device authorized quickly without the risk of receiving a warning letter later?

Bottom line: Like all pathways to market, the EUA has the potential to get lifesaving medical devices to patients quickly who desperately need them. But if used improperly, the EUA has the potential to make things even worse than they already are. Its up to us as medical device professionals to use the EUA *responsibly* to achieve speed to market and safety at the same time!

What to know more?

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

Speaker Biography



Michael Drues, Ph.D., is President of Vascular Sciences, an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including stimulating & innovative educational programing, creative regulatory strategy & 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.

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my video, my brochure, my vision...

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Introductions



How can Medical Device Companies use the EUA to Address the COVID-19 Pandemic?

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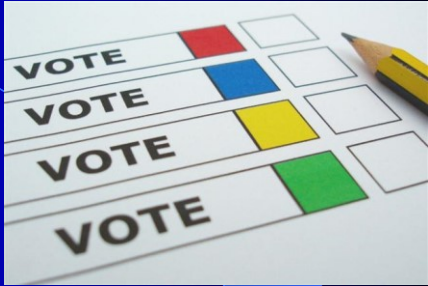
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Before we begin...


Polling Question



Have you already used the EUA?
If YES, for an existing device? a new device?
Do you plan to use the EUA?
Have you used/are using another pathway (in the US)?



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

- ✓ What is the Emergency Use Authorization (EUA) and how do we use it?
- ✓ Which devices qualify for EUA and which do not? Does it matter if it's an existing/new device?
- ✓ What are the regulatory requirements for the EUA and what's the process for applying?
- ✓ What are the testing requirements? How do we find them? How much evidence is required?
- ✓ If the EUA is not applicable, what other options exist?
- ✓ What are the quality and validation requirements for COVID-19 related devices?
- ✓ How should we modify our QMS for devices used during the COVID-19 crisis?
- ✓ How do we handle devices coming back from the field, i.e., devices recalled from hospitals?
- ✓ What happens to devices with EUA after this public health crisis is over?
- ✓ How can we get a device authorized "quickly" without risk of receiving a warning letter later?
- ✓ Lots more tips and tricks... time permitting!
- ✓ Final thoughts...

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Want more?


PODCASTS

Mike on Medtech: COVID-19, Part 1
Mike Drues and Sean Fenske discuss Emergency Use Authorization and the potential problems with non-medical device manufacturers producing ventilators.



PODCASTS

Mike on Medtech: COVID-19, Part 2
Mike Drues and Sean Fenske discuss issues involved with misinformation around products to help treat COVID-19 and relaxed regulatory rules.



PODCASTS

Mike on Medtech: COVID-19, Part 2
By Sean Fenske, Editor-in-Chief • 04.08.20
In this Medtech Matters podcast episode of Mike on Medtech with Mike Drues, president of Vascular Sciences, we discuss recent coverage of a two-minute COVID-19 test that had miscommunicated obtaining emergency use authorization from the FDA. We look at actions the FDA is taking around these types of incidents and also about the potential issues with a

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EMERGENCY USE AUTHORIZATION (EUA) 101: WHAT MEDICAL DEVICE COMPANIES NEED TO KNOW


By Nick Tappan, April 8, 2020 • FDA Regulations and Regulatory Compliance and Global Medical Device Product and Regulatory Affairs and Mike Drues and Medical Device Product and Medical Device Industry and Manufacturing.



What qualifies and what does not for Emergency Use Authorization (EUA)? What is the impact of this regulatory pathway during the COVID-19 pandemic?

In this episode of the Global Medical Device Podcast, Jon Sorenson talks to Mike Drues of Vascular Sciences™ highly relevant discussion about how medical device professionals may consider EUA as a way of getting bring a medical device to market that can support the needs of healthcare providers and patients.


LISTEN NOW:



MPO Podcast: Part 1 [here](#) / part II [here](#) GreenLight.Guru Podcast [here](#)

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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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What is the Emergency Use Authorization (EUA) and how can I use it








Beginning with the basics... then beyond!

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CORONAVIRUS (COVID-19)

Emergency Use Authorization
Emergency Use Authorization (EUA) information, and list of all current EUAs

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Strategic Recommendation:
Want to have a successful EUA?
Parse these words carefully...
Otherwise, you're wasting FDA's time... and yours!

What is the emergency use authorization (EAU)?
"allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological and nuclear defense threats by facilitating the availability and use of medical countermeasures needed during public health emergencies."
"may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives."
EAU Previously used: Anthrax, Ebola Virus, H7N9 Influenza, Zika Virus, a few others

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What are medical countermeasures?

"FDA-regulated products" (biologics, drugs, devices) that may be used in the event of a potential public health emergency."

Note:
"FDA-regulated products" excludes wellness devices!
i.e., Wellness Device ≠ CFR Definition of Device

But beware...

Make sure you can support your claims!

↓
FTC, FDA, FBI

Updated March, 2020 [here](#).

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What are the ramifications for making unsubstantiated claims and/or not doing necessary testing

Consider this:

FDA has issued almost as many warning letters as EUA's!

EUA or not... you are ultimately responsible!

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What's happening now?

Don't buy these 'false' coronavirus treatment claims, FTC warns
Feds target unsubstantiated COVID-19 treatment claims
Fox Business, April 14, 2020 [here](#)

FTC warns firms over unproven COVID-19 treatment claims
FTC: sent warning letters to >25 companies to **stop making unsubstantiated claims** that their products could prevent or treat COVID-19.

Regulatory 101: ***You need to be able to substantiate your claims!***

FDA: ***currently no products scientifically proven to prevent or treat the coronavirus.*** Andrew Smith (FTC) said it was **"shameful to take advantage of people by claiming that a product prevents, treats or cures COVID-19."** ... "We're seeing these false claims for all sorts of products, but anyone who makes them simply has no proof and is likely just after your money," Smith said.

Shameful is not the word I would use!

What are the ramifications?
Taking away resources for evaluating legitimate products... making it more difficult for everyone else!

FDA was created June 30, 1906 (Medical Devices: May 28, 1976) yet
These things still happen today – why? What should industry do about this?

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When can the EUA be used



Criteria for Emergency Use Authorization initiation:

- **domestic emergency involving a heightened risk of attack** with a chemical, biological, radiological, or nuclear (CBRN) agent;
- **military emergency with a heightened risk of an attack** with a CBRN agent on U.S. military forces;
- **a public health emergency** affecting or with **the significant potential to affect** national security or **the health and security of U.S. citizens** living abroad, that involves a CBRN agent or related disease or condition; or
- **a material threat sufficient to affect** national security or the health and security of U.S. citizens living abroad.

Clearly the EUA was never intended for disease pandemics... but it's the closest thing we have so why not use it?

EUA criteria and requirements need to be updated for the future.

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What types of products thus far

- ✓ First COVID EUA issued Feb 4, 2020 – CDC Real-Time Reverse Transcriptase Diagnostic Panel
- ✓ FDA issued ~35 EUAs to manufacturers/labs for various IVD's – **clearly the majority!**
- ✓ Additional EUAs for personal protective equipment, 3 respirators, 1 face shield
- ✓ Other EUAs include:
 - 4 reprocessing devices for decontamination/sterilization
 - 1 ventilator
 - 2 extracorporeal blood purification devices
 - 1 therapeutic product (chloroquine)
 - 3 for other devices, i.e., pumps, diaphragm pacing systems

FDA's Emergency Use Authorizations (April 20, 2020) [here](#)

Number don't matter... types of devices/technologies does!

Strategic Recommendation:



Getting an EUA for a device that's similar (i.e. SE) to above is relatively easy...

Getting an EUA for a device that's different... not so much!

Even in the EUA world, there are many me-too's! ☺

Regulatory 101:

The more similar you are the easier... the more different, the more difficult! [think ventilators!]

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How long will the Emergency Use Authorization (EUA) last

Until HHS says the emergency is over but... the window is closing... (fast?)

[Note: this is a political decision]

Two scenarios:

1. For companies with existing EUAs, *what happens to your device after?*
2. For companies pursuing an EUA now, *is it still worth it?*

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Where does the Emergency Use Authorization (EUA) fit within the medical device universe



First and foremost: only available at certain times!

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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 (EUA)**

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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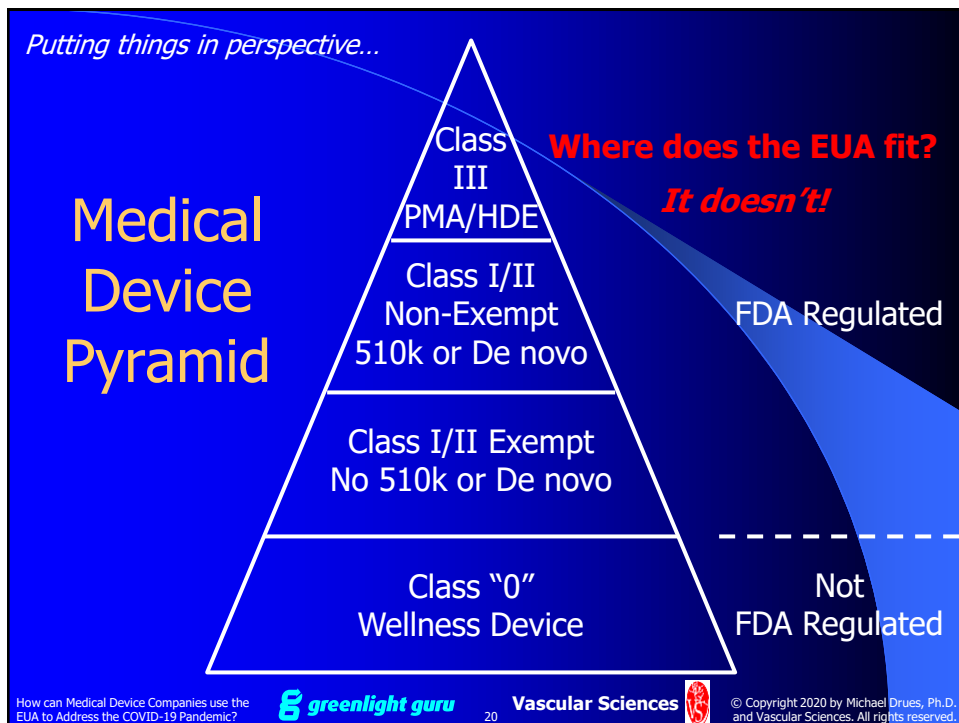
Presenter
MICHAEL DRUES, PH.D.
President at Vascular Sciences

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

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What goes into an EUA



Components of an EUA request:


- ✓ Device description
- ✓ High-Level Labeling: indications for use, intended use, COVID-specific claims (meet EUA criteria)
- ✓ Low-level labeling: directions for use (DFU), Fact Sheets for health care professionals and feasibility of providing this information in an emergency
- ✓ Device's FDA approval status, i.e., existing device vs. new device
- ✓ Demonstration of need, i.e., are there adequate, approved, and available alternatives
- ✓ Safety and efficacy, i.e., literature, bench-top, animal, RCT, RWE (my favorite)
- ✓ Risk-Benefit analysis including risk mitigation strategy (very different in public health emergency)
- ✓ Manufacturing info, i.e., chemistry, manufacturing controls, sites of manufacture, cGMP status
- ✓ Quantity of product on-hand/manufact capabilities – *scale up... can you meet the market need?*
- ✓ Support for extension of label expiration date if applicable
- ✓ Right of reference to rely upon data submitted by others

Very little that's different from a traditional medical device submission!

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How about an example?



TransAeris used to assist in weaning patients determined by their healthcare provider to be at high risk of weaning failure off of ventilators in healthcare settings during the COVID-19 pandemic for no more than 30 days.

Device to Assist in Weaning Patients Off Ventilators is Granted EUA [here](#). / www.synapsebiomedical.com/

FDA EUA Letter [here](#):

"The above described product, when labeled consistently with the labeling authorized by FDA... is authorized to be distributed under this EUA, **despite the fact that it does not meet requirements otherwise required** by applicable federal law.



"...it is reasonable to believe that the known and potential benefits of the authorized TransAeris Diaphragm Pacing System, when used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such products."

"...**based on the totality of scientific evidence available** to FDA, that **it is reasonable to believe that the authorized TransAeris Diaphragm Pacing System may be effective for emergency use in** treating patients by assisting in weaning patients off ventilators in healthcare settings during the COVID-19 pandemic when used consistently with the Scope of Authorization of this letter."

"This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated" – **what happens afterwards?**

"**FDA is waiving applicable cGMP requirements, including the quality system requirements** under 21 CFR Part 820 **with respect to the design, manufacture, packaging, labeling, storage, and distribution** of the authorized TransAeris Diaphragm Pacing System that is **used in accordance with this EUA.**" – **is this a good thing?**

"[Company] will have process for **reporting adverse events of which they become aware to FDA.**" – **given device "does not meet requirements" is passive PMS enough?**

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When and how to I contact FDA





HOW TO FILE A PRE-EUA FOR A COVID-19 DEVICE



STEP 1:	STEP 2:	STEP 3:
 <p>For in vitro diagnostics (IVD), email CDRH-EUA-Templates@fda.hhs.gov. For non-IVDs, email CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov Request a copy of the most recent emergency use authorization (EUA) review template. Include a brief description of the technology.</p>	 <p>Populate the draft template with the information and data that you currently have, then send it back to FDA for review. Follow the instructions that are provided along with the review template (which includes sending one hard copy and one electronic signature copy to the document control center).</p>	 <p>The pre-EUA review is a very interactive process. The draft review template is a shared work-in-progress document. FDA will review the information on your draft template and provide feedback. For questions about the process, contact the agency's 24-hour hotline: 1-888-INFO-FDA, choose the "star" option (*).</p>

When?
When you have most if not all of your ducks in a row... and not sooner!
 This is not take a number & get in line...
 FDA is triaging all EUA requests... as they should!

Remember,
Don't waster FDA's time... or yours!

How?
 ← Step-by-step recommendations on how to seek EUA **for COVID-19 tests, ventilators, and personal protective equipment.**
What about other devices?

Important:
This should be a collaborative process!
 A Comprehensive Guide to COVID-19 EUA Submissions [here](#)

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What are the testing requirements for an EUA device



In most situations... there are none! Nor should there be!

1. Forget COVID: Identify all tests necessary for a "normal" (non-EUA) device?
 Where do I look:
 - Forget COVID – look at guidance, standards, "predicates" – all sources
 - General COVID i.e., EUA Guidance
 - Product-Specific COVID Guidance (if any)
2. Triage list based on risk, i.e., S&E vs. everything else
3. Sell to FDA, i.e., interactive EUA process *substantially equivalent* to pre-sub

Note: Pun intended! ☺

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What if I modify my existing device for COVID



Modify existing device vs. Create new device

Remember: lots of me-too EUAs... very, very, very few new and novel EUAs (think ventilators)

Any different in the non-COVID world, i.e., 510k vs. de Novo?

Bottom line, *absolutely nothing new here*... Regulatory 101:

Need to support changes in labeling and/or changes in technology... EUA or not!

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CORONAVIRUS (COVID-19)

What does FDA say?

Emergency Use Authorization (EUA) [here](#)

Emergency Use Authorization

Emergency Use Authorization (EUA) information, and list of all current EUAs

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Content current as of: 04/01/2020

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Emergency Response
Drug Shortage
Terrorism
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Outbreak
Chemical
Biological

Health Topic(s)
Coronavirus

What about modifications to existing devices (i.e., devices already on market for something else)?

Guidance: *Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019* (Mar, 2020) [here](#)

Purpose: non-invasive remote monitoring devices to facilitate patient monitoring while reducing patient and healthcare provider contact and exposure

Duration: **remain in effect only for the duration of the public health emergency**

Important Disclaimer: FDA **does not intend to object** to **limited modifications** to the indications, claims, functionality, or hardware or software of **[an already] FDA cleared** non-invasive remote monitoring devices that are used to support patient monitoring **during the declared public health emergency**

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How do I modify my QMS for EUA devices



YES, you should have QMS for EUA devices – EUA is not an excuse to be sloppy!
What about PMS? With limited data to support safety and efficacy,
PMS for EUA maybe more important than other times!

Most important:
Although some quality requirements have been relaxed... quality principles still apply!

Consider this:
What is worse?
Not having enough ventilators or having a bunch of ventilators that don't work?
Not having enough diagnostics or having a bunch of diagnostics that are not accurate?

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Haste makes Waste... or Worse?

"LA County got 170 broken ventilators from feds... silicon valley is fixing them."
LA Times, March 30, 2020 [here](#).

This was 100% predictable!

So what's worse?
Not having enough ventilators...
or
Having a bunch of ventilators that don't work?

Is it possible to have enough ventilators that work?
Absolutely YES!

Take-aways:

- ✓ Importance of having a good QMS
- ✓ One would like to think QC tested ventilators before releasing to hospitals
- ✓ Suffocating 179 patients using malfunctioning ventilators would not a mistake I would want to make!
- ✓ Personal e-mails from FDA expressing concerns

News Video: Can Tesla, GM And Ford Help Solve The Coronavirus Ventilator Shortage? (CNBC, Mar 27, 2020) [here](#)
FDA Ventilator EUA Letter [here](#) (3/24/20)



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Does EUA lower the bar compared to other pathways to market



Regrettably yes... should it?

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CORONAVIRUS (COVID-19)

Emergency Use Authorization
Emergency Use Authorization (EUA) information, and list of all current EUAs

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Emergency Use Authorization (EUA) [here](#)

Does EUA lower the regulatory burden compared to other pathways to market?

According to FDA... YES (e.g., hand sanitizers, PPE, i.e., face masks, etc.), but should it?
Waving FDA Registration? – *Ok but... still should meet quality reqmts, design controls, etc.*
Waving GMP Requirements? – *Absolutely not... will likely cause more problems than it solves!*

EUA should be similar to BDP... same regulatory burden but more efficient path to market!

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Should we lower the bar



FDA urged to keep drug approval standards amid pandemic

"FDA should maintain its standards for drug approval amid the COVID-19 pandemic following the agency's decision to grant emergency use authorization to chloroquine and hydroxychloroquine despite limited evidence of their efficacy... *Advocating that the FDA should quickly approve drugs without randomized trial data runs counter to the idea of evidence-based medicine and risks further undermining the public's understanding of and faith in the drug-review process.*"

RAPS/New England Journal of Medicine (April 15, 2020) [here](#).

Any different for medical devices? Should it be?

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Lowering the bar


ECMO and Cardiopulmonary Bypass Devices

- ✓ long-term extracorporeal oxygenation is needed to treat some patients with COVID-19 who experience acute respiratory or cardiopulmonary failure.
- ✓ **FDA says it will not object to certain modifications to already cleared ECMO or cardiopulmonary bypass devices** during the public health emergency without prior 510(k) notification to expand their availability and use, **so long as the modifications do not pose an undue risk to patients. – what constitutes "undue risk" and how do we demonstrate it?**
- ✓ FDA will allow modifications to cardiopulmonary bypass devices including changes to the device's indications to include use in an ECMO circuit, to allow more than six hours use in an ECMO circuit and to allow modifications to accessories for both ECMO and cardiopulmonary bypass devices that do not affect the flow rate of blood through the circuit.
- ✓ FDA says it considers certain modifications to pose an undue risk to patients, including changes to device coatings and changes that could negatively impact the gas transfer/exchange properties of the device.
- ✓ labeling recommendations and FDA-recognized consensus standards for designing, evaluating and validating such modifications – **do we really need this?**
- ✓ FDA interested in working with manufacturers **to grant emergency use authorizations (EUAs) for ECMO and cardiopulmonary bypass devices that are not currently legally marketed in the US.** In some instances, FDA says it will allow the distribution and use of a non-legally marketed device while the company is still preparing an EUA request.
- ✓ FDA notes that the guidance does not apply to extracorporeal carbon dioxide removal devices "because such devices may not oxygenate the blood at clinically meaningful levels." However, FDA says manufacturers of such devices may consider requesting an EUA.

What about "new" ECMO devices? When does a modified device become a new device?

Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19)

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Lowering the bar

Ophthalmic Devices

- ✓ **FDA will not object to a range of modifications without 510(k) notification for devices falling under seven product codes** encompassing visual acuity charts, visual field devices, general use ophthalmic cameras and tonometers.
- ✓ **Permissible modifications are broken up by device type**, with FDA providing a set of allowable modifications for visual acuity charts, visual field devices and general use ophthalmic cameras and a separate set of modifications for tonometers.
- ✓ Allowable modifications include changes to indications or functionality to allow for patient monitoring or assessment; home use by consumers; and remote assessment for telemedicine consultations.
- ✓ FDA says the policy does not cover devices "intended to determine when patients need immediate clinical intervention to assure patient safety" or devices "intended to be solely or primarily relied upon by the eye care provider or patient to make a clinical diagnosis or treatment decision."
- ✓ For tonometers, FDA says that limited modifications may be permitted for devices that are only intended for measuring intraocular pressure; are handheld or portable; operate with a non-contact, rebound or transpalpebral mechanism; are intended for supporting or providing adjunctive recommendations to eye care providers; and "allow for eye care providers to independently review the basis for any diagnostic or treatment recommendations."

Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

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Where is the balance?



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FDA Warns Against Fraudulent COVID-19 Tests and Treatments

The agency's warning comes at a time when there are 61,062 COVID-19 cases reported in the U.S., with 838 deaths, and 387 recovering.

By Omar Ford
March 25, 2020 in *Regulatory and Compliance*

Thus far FDA has issued almost as many warning letters as EUA's!

FDA Warns Against Fraudulent COVID-19 Tests and Treatments [here](#)

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Let's help him. But will we get into trouble with the police?

We are protected by the Good Samaritan Law. I am calling for emergency response!



Should I worry about Product Liability for EUA devices

Does the "good Samaritan" principle apply?

"...offer legal protection to people who give reasonable assistance to those who are, or whom they believe to be, injured, ill, in peril, or otherwise incapacitated." [here](#)

Note: Varies state to state.

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Remember...

If you are coming from outside the medical device world, thanks for your help but you still need to know what you are doing!



The road to hell is paved with good intentions

CLICK
↓



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What are the takeaways a.k.a. common-sense advice



Things to remember about the EUA:

1. Temporary authorization – *have a long-term strategy*
2. Have realistic expectations – *take what politicians say with a grain of salt!*
3. Existing device (↓RB) vs. new device (↑RB) – *as it should be!*
 - Lowest regulatory burden → no changes in design (make “exactly the same” as existing cleared/approved device)
 - Any changes to design, materials, MOA, etc. increase regulatory burden – as it should!
4. Don’t waste FDA’s time... or yours! – *be prepared!*
Many EUAs are a waste of FDA’s time/resources because the company did not do their homework!
5. Not an excuse to take shortcuts – *safety & efficacy are always key!*
This is really not that complicated... nor should it be!

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

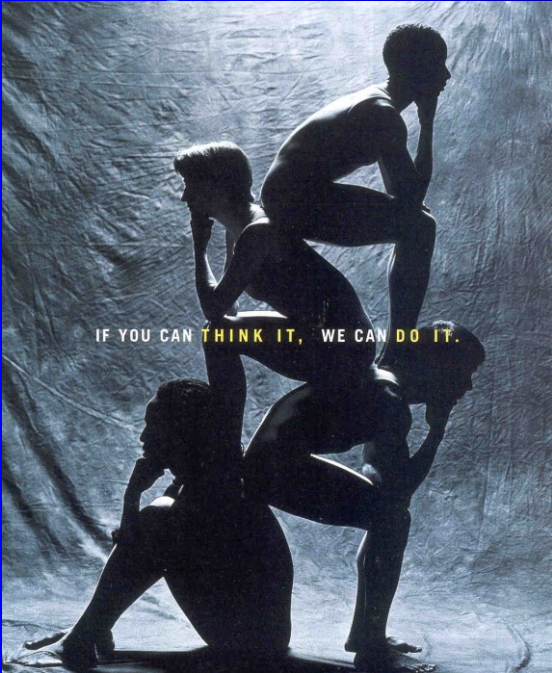


Rules are mostly made to be broken and are too often for the lazy to hide behind.

General Douglas MacArthur (1880 –1964) was an American general in the US Army during the 1930s and played a prominent role in the Pacific theater during World War II. He was one of only five men ever to rise to the rank of General of the Army in the U.S.

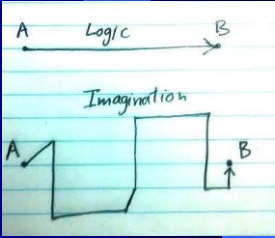
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"Imagination is more important than knowledge, for while knowledge points to all there is, imagination points to all that can be."

Albert Einstein



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

Albert Einstein

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