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

For questions or more information, call
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How can Medical Device Companies use the Emergency Use Authorization (EUA) to Address the COVID-19 Pandemic?

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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 & completive regulatory intelligence, regulatory submission design, FDA presentation preparation & defense, brain-storming sessions, prototype design, product development, benchtop & animal testing, , clinical trial design, reimbursement, clinical acceptance, business development & technology assessment.

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

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

Finally, as an Adjunct Professor of Regulatory Science, Medicine, Biomedical Engineering & Biotechnology, Dr. Drues teaches graduate courses in Regulatory Affairs & Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs & Product Development, Combination Products, Pathophysiology, Medical Technology & Biotechnology at several universities & medical schools on-ground & on-line.

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

Introductions

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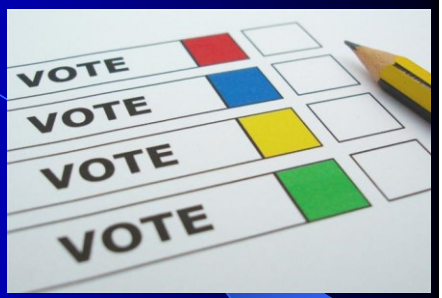
Before we begin…

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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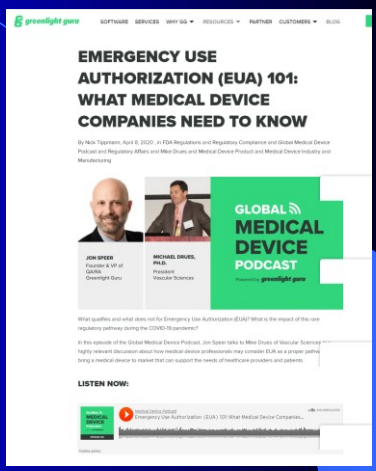
Want more?

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

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

Beginning with the basics… then beyond!

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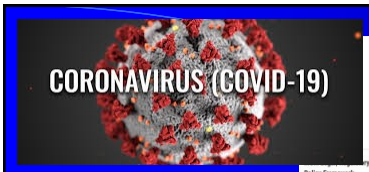

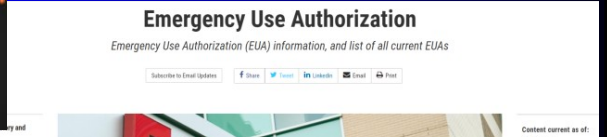

Strategic Recommendation:

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

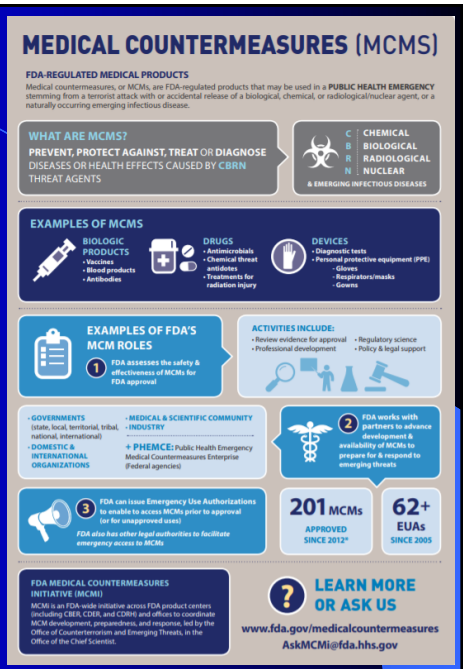
But beware…

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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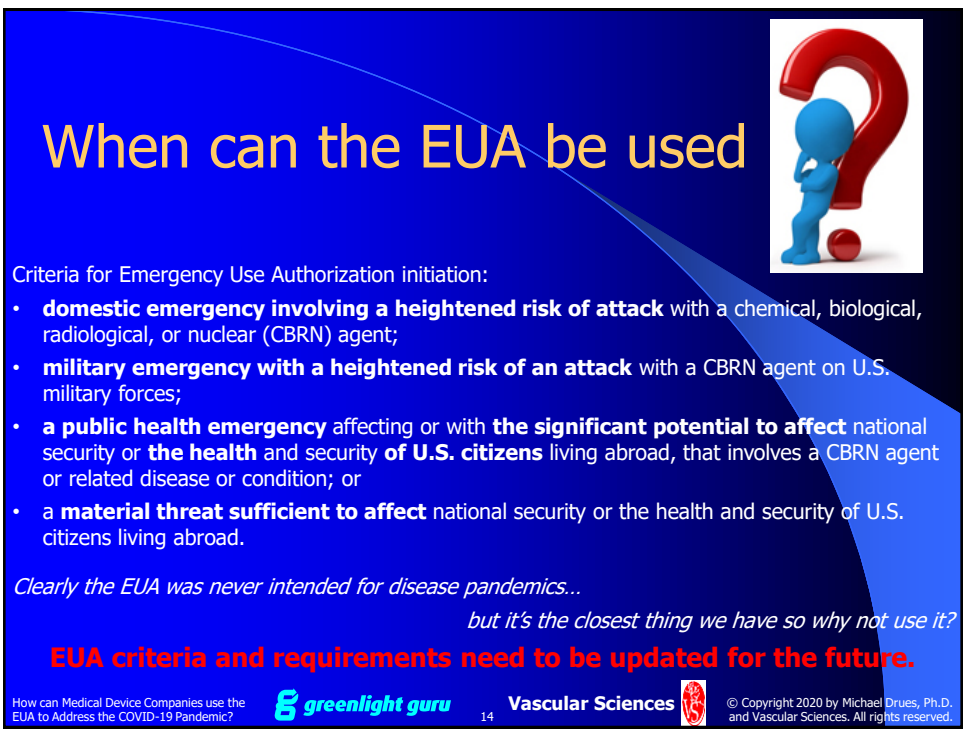

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How can Medical Device Companies use the Emergency Use Authorization (EUA) to Address the COVID-19 Pandemic?

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 EUA's, *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 (EAU)**

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

Plus:

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

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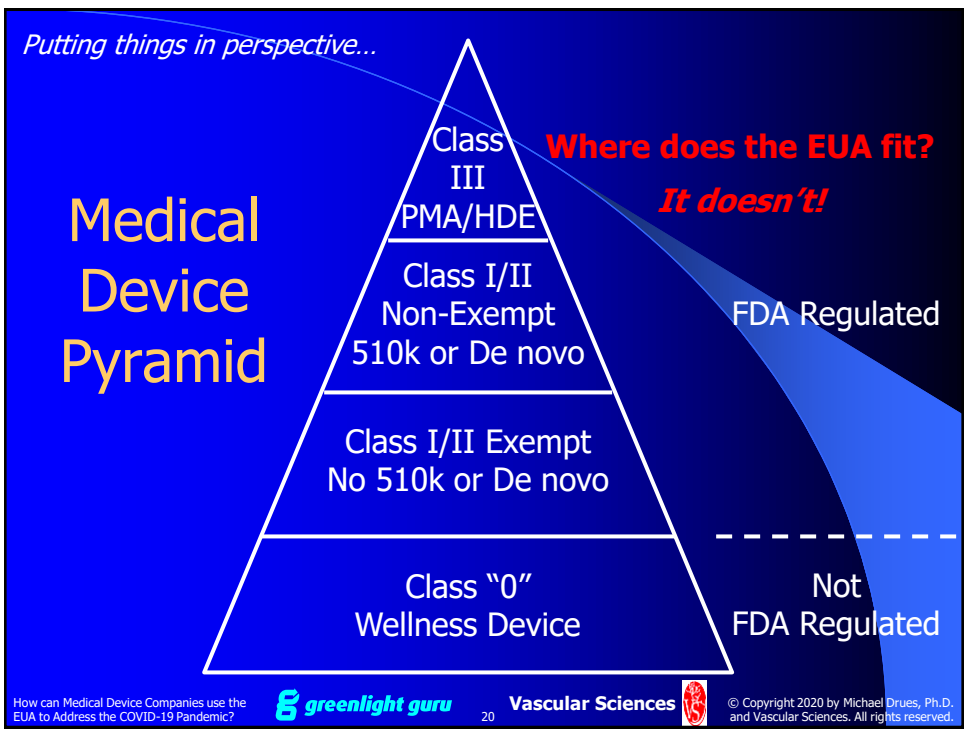

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How can Medical Device Companies use the Emergency Use Authorization (EUA) to Address the COVID-19 Pandemic?

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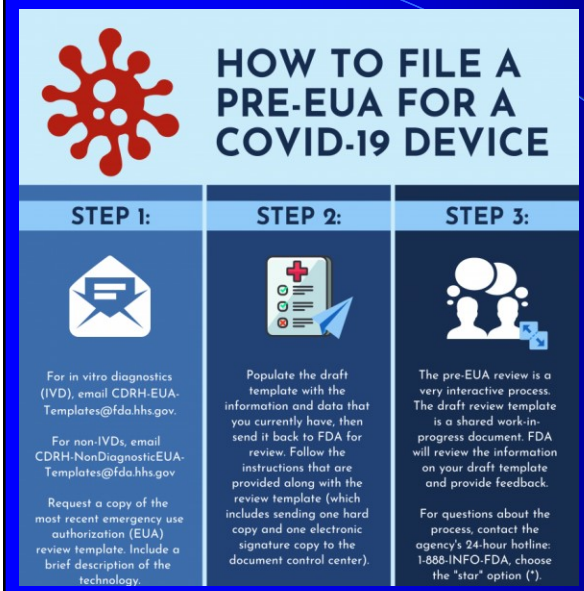
How can Medical Device Companies use the Emergency Use Authorization (EUA) to Address the COVID-19 Pandemic?

When and how to I contact FDA



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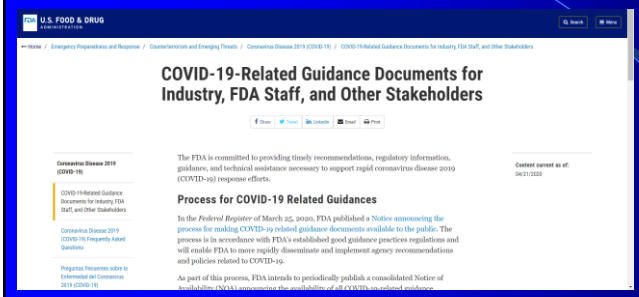
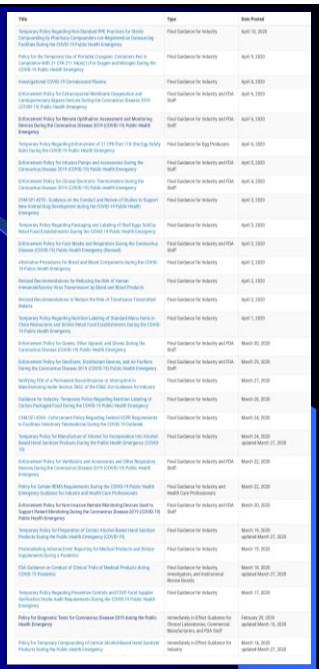
How can Medical Device Companies use the Emergency Use Authorization (EUA) to Address the COVID-19 Pandemic?

COVID-19-Related Guidance Documents





Currently ~35 COVID-Related Guidance Documents

However,

Like all guidance, there "usefulness" is debatable

(remember they are written for a very broad audience)

but you should be aware of them… that's your job not FDA's!

COVID-19-Related Guidance Documents here.

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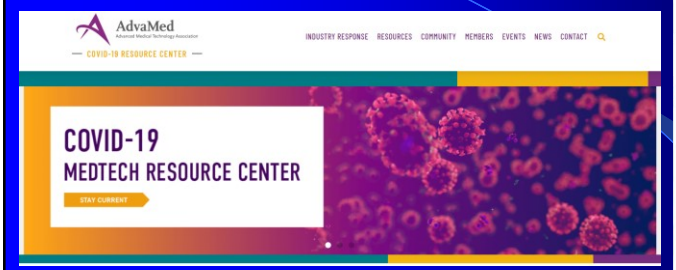
Want more?



AdvaMed COVID-19 MedTech Resource Center here

Things are changing and evolving quickly…

but that's no excuse not to keep up!

Side note: Jean-Baptiste Alphonse Karr said

The more things change, the more they stay the same.

So there is really very little new here…

if you understand the regulatory logic!

MDDI COVID-19 News Central here

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

What if I modify my existing device for COVID

Modify existing device vs. Create new device

Remember: lots of me-too EUA's… very, very, very few new and novel EUA's (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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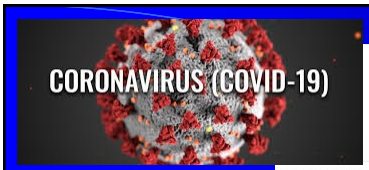
What does FDA say?



Emergency Use Authorization (EAU) here

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

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.

California Gov. Gavin Newsom, second from right, tours the Bloom Energy Sunnyvale, Calif., campus Saturday. Bloom Energy is a fuel cell generator company that has switched to refurbishing ventilators. (Beth LaBerge/KQED via AP, Pool)

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 EAU Letter here (3/24/20)

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

Does EUA lower the bar compared to other pathways to market

Regrettably yes… should it?

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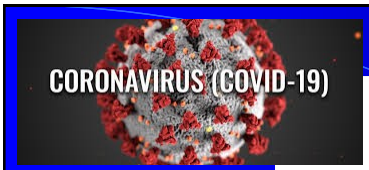

Emergency Use Authorization (EAU) here

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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April 22, 2020

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

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

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

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

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!

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

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

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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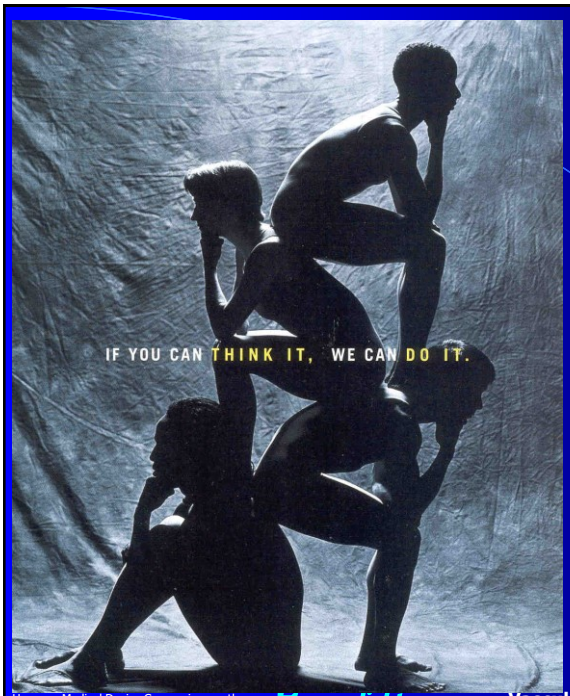
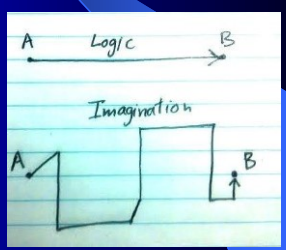


"Imagination is more important than knowledge, for while knowledge points to all there is, imagination points to all that can be."

Albert Einstein



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

Albert Einstein

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