Understanding Medical Devices During the Pandemic

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Speaker

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Disclaimer

- Darren Reeves is a consultant and not with the FDA.
- Everything in this presentation is his current understanding of the current situation.
- Darren has been in touch with the FDA on several topics.
- Darren has been working with the FDA for 30+ years, but we all know nothing like this has ever happened.

Agenda

- Types of devices of concern during pandemic
- Device classes
- What is PPE?
- Differences in devices
- Emergency Use Authorization (EUA)
- Factory requirements
- FDA Approval
- Hand Sanitizer/Alcohol for Hand Sanitizer
- Current status (things changing every day)

Webinar Flow

- Going to try to get through this presentation in 30 mins.
- If you have a question, please note the slide number at the bottom so we can efficiently address in the Q&A.
- After the presentation I expect to have a 30 Min Q&A, but I do not have a hard stop today since this is a pressing topic.
- If your question will take longer than we have or it is very specific, I may just say “Call Me” (804-307-7706)

Types of Devices

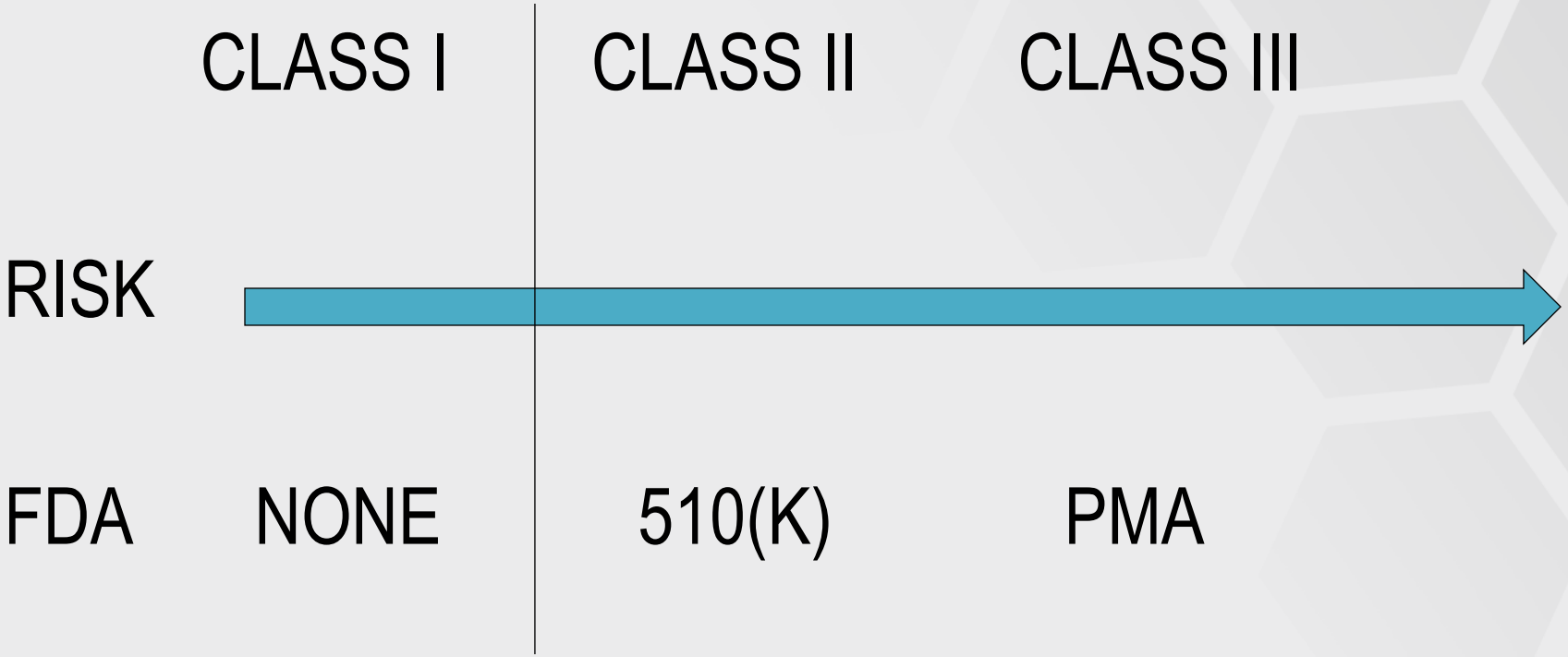
- Masks
- Face Shields
- Gowns
- Gloves
- Coveralls
- Ventilators
- Hand Sanitizer/Alcohol (actually drugs)

Device Classes

- The FDA classified devices into 3 classes based on the level of regulatory oversight they believe is required.
- Class I – Lowest Risk
- Class II – Medium Risk
- Class III – Highest Risk

- The amount of oversight depends on the class.

Device Classes



What is PPE

- PPE stands for Personal Protective Equipment.
- Personal protective equipment is protective clothing, helmets, goggles, or other garments or equipment designed to protect the wearer's body from injury or infection.
- The hazards addressed by protective equipment include physical, electrical, heat, chemicals, biohazards, and airborne particulate matter.

What is PPE

- This is a common term in a lot of industries.
- With respect to the pandemic, PPE specifically needed are:
  - Masks
  - Face Shields
  - Gowns
  - Gloves
  - Coveralls

Differences in Devices

- 2 Types of Masks
- N95/Respirators – Class II – Under EUA

Differences in Devices

- The N95 is also called a Respirator.
- Some people may call a “Ventilator” a respirator. Make sure you are clear on what they are talking about.
- The N = NIOSH
- 95 means it filters 95% airborne particulates.

Differences in Devices

- Surgical Mask – Class II
- Rectangular pleated mask with ties or loops
- At this time require a 510(k) from the FDA.

Difference in Devices

- The following PPE are Class I devices and can be made and sold almost immediately:
  - Head Covers
  - Shoe Covers
  - Scrubs
  - Coveralls
  - Patient Gowns (Not surgical Gowns)
  - Patient Exam Gloves

Differences in Devices

- Surgical Gloves
  - Class II – Require 510(k) from the FDA as they are surgical gloves.

Differences in Devices

- Patient Exam Gloves
  - Class I – Can produce immediately.

Intended Use

- Some of these issues are grey.
- The FDA regulates devices based on the claims made by the manufacturer. If any medical claims are made, to include infection prevention, they are regulated.
- You may see gloves and masks sold at Walmart or CVS that are not regulated because they are sold for industrial use, not medical use.

Emergency Use Authorization (EUA)

- This allows certain things to be used in an Emergency.
- It is an application that must be submitted to the FDA.
- Right now both N95 industrial masks and Coronavirus tests are under EUA.

Factory Requirements

- “Normally” every medical device must be made under Good Manufacturing Practice (GMP) conditions.
- GMPs for medical devices are called the Quality System Regulation (QSR) and are codified under 21 CFR Part 820.

Factory Requirements

- ISO 13485 and ISO 9001 are both types of quality systems and are very close to the QSR.
- There are several methods in which we can help support this quickly, from developing quality plans to implementing template SOPs.
- We can help in all situations.

FDA Approvals

- Determine if the company wants to do the activity short or long-term.
- If long-term then they may need a type of FDA approval.
- BE CAREFUL! FDA only approves Class III devices.

FDA Approvals

- Class I devices
  - Must have QSR procedures.
  - Must register the facility (just says “I am here”). Cost is $5,236 for 2020.
  - Must list the type of devices dealt with by 3 letter FDA code.
  - We can do this for the company.

FDA Approvals

- Class II

- Same as Class I but…
- Normally needs a 510(k), which is a "marketing approval" and not a device approval.
- There is a list of devices that are exempt from 510(k) or have enforcement discretion.
- FYI, ventilators are Class II.

FDA Approvals

- Class III
  - Life-sustaining devices
  - You probably will never deal at this level.
  - Same as Class II but instead of 510(k) marketing approval they need a Premarket Approval (PMA). Costs millions and takes years typically.

Hand Sanitizer/Alcohol

- These are actually pharmaceuticals.
- The FDA has implemented “Enforcement Discretion” on the making of hand sanitizer and the alcohol used in the hand sanitizer under very strict guidance.

Hand Sanitizer/Alcohol

- Search for the following documents for the requirements:
- *Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency*
- *Temporary Policy for Manufacture of Alcohol for Incorporation Into AlcoholBased Hand Sanitizer Products During the Public Health Emergency (COVID-19)*

Other

- Things are changing daily.
- As we get additional information, we will disseminate it to the group.

Future Support

- This is all going to blow over and life will get back to normal, but life is going to change as well.
- It is our opinion that the medical device industry will grow dramatically due to the current administration and this pandemic.
- Our company can support you now and in the future.

Questions

What questions do you have???

Stay Informed

Contact Us for Follow Up Regarding your PPE Questions:
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