Understanding Medical Devices During the Pandemic
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

<table>
<thead>
<tr>
<th>CLASS I</th>
<th>CLASS II</th>
<th>CLASS III</th>
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<tbody>
<tr>
<td>RISK</td>
<td>FDA</td>
<td>NONE</td>
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<tr>
<td></td>
<td>NONE</td>
<td>510(K)</td>
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<td>PMA</td>
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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.
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 Alcohol-Based 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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