



DP Distribution & Consulting, LLC

12240 Hunting Horn Lane, Rockville, VA 23146>Phone:804-307-7706><http://www.dpdonline.com>

Dated: March 28, 2020

Webinar: Understanding Medical Devices During the Pandemic | Q & A

1. Hand sanitizer: What if you are making the glycerol portion?
Only the APIs (Active Pharmaceutical Ingredients) are regulated by the FDA. Glycerol is a non-API and is not regulated by the FDA.
2. Is hand sanitizer Class I?
No. Hand sanitizer is a pharmaceutical and not a medical device.
3. The hand sanitizer manufacturing – I heard that they do not need to register at the FDA site now...but do they if they are going to continue to after the crisis?
Yes. The facility registration exemption is only for the duration of the State of Emergency.
4. If we are making hand sanitizer, do we need to register with the FDA? Is the answer the same if we are making the alcohol for hand sanitizer?
During the State of Emergency, you do not have to register with the FDA to make hand sanitizer. You do have to register with the FDA if you make the alcohol for the sanitizer but it is a simple on-line registration and you do not have to wait for anything to begin manufacturing.
5. There are some companies that would like to participate in the PPE supply chain but do not know how to get started. Exactly what service is Darren offering MEPs to help their clients become a successful supplier?
Darren can provide any medical device activity support. The starting point would be to identify what product the company provide, what type of manufacturing environment they currently have and do they want to do this short or long term. Once that information is obtained you can contact Darren for further direction.
6. Is there a list or website that breaks everything down into class I, class II and class III?
See the following link. Once there, in the “Devie” block type in a generic medical device name (e.g. mask, cover, gown) and search.
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/classification.cfm>
7. What about home sewists making masks? Have heard some medical professionals are putting over n95 to extend use. Also, clinics are using for patients. Any guidance?
The FDA is not enforcing “normal” regulations for home sewists during the State of Emergency. There are several guidance locations on-line as to how to manufacturer these products safety. See the following link as an example.
<https://www.health.state.mn.us/diseases/coronavirus/hcp/masksalt.pdf>



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8. Is a face mask Class I and do you need to register?
Surgical Face Masks are class II and “Normal” require a 510(k). During the State of Emergency you do not need to register with the FDA. There is some guidelines you need to follow which are in the following link:

<https://www.fda.gov/media/136449/download>
9. Are plastic shields Class I?
Yes. Plastic face shield are class I devices.
10. If we want to make/sell face shields short term, what do we need to do?
You can begin making them immediately. The FDA has given State of Emergency exclusion to manufacturing GMPs during this time.
11. What is your advice for manufacturers wanting to help with Class II masks? Should we focus on Class I masks? Wait a few weeks on Class II? What is the shortest timeframe for Class II approval?
For the Class II devices such as masks, the FDA has put out additional guidance since the webinar that they are exempting manufacturing requirements under certain guidelines in the link to number 8 above. So you can begin manufacturing those now. It typically takes about 60-90 days for FDA 510(k) once the submission is sent.
12. I heard surgical masks, surgical gowns, syringes, catheters for example need a 510(k). What about Class I devices?
Most Class I devices do not require a 510(K). You can contact us for confirmation or follow the link in question #6 above and research.
13. Do masks require sterilization? What are the packaging requirements to maintain sterilization?
Masks do not require sterilization. For products that need sterilization the process must be validated. That is one of my specialties so if you have further questions on that please contact me.
14. I am part of local government and we are getting a lot of offers for PPE available, what are some of the checks to vet a manufacturer making claims of providing PPE?
Here are ways to vet: Check if the manufacturer is registered with the FDA and if they have that product listed. Check if the product has a 510(k) if required (although they now do not need one during the State of Emergency). Check their D&B number. View samples.
15. I have a client that makes artificial lung devices that are already in 36 US research hospitals on a trial basis and are proven to help COVID 19 patients. They applied for an EUA. They are asking the FDA to review their EUA ASAP! Will it help to have our Congressional delegation



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send a letter asking that their application move to the front of the line? It could literally be saving lives today!

Yes, that would help. Also, see the following information I received from the FDA which describes a process during the State of Emergency that gives the special e-mail address set up for these types of issues.

Dear DARREN REEVES,

FDA is seeking information from manufacturers for the national emergency response to the novel coronavirus (2019-nCoV) outbreak. We are reaching out to you to collect information on personal protective equipment (PPE), including masks, respirators, gowns, and gloves, that may be used to prevent the spread of infection. We have identified your firm in our Registration and Listing database as a manufacturer or contract manufacturer of these medical devices.

To provide us with a clear picture of the current availability of PPE, we would appreciate your prompt reply to the questions in the attachment with as much information as you currently have available. If you can obtain more information later, we ask for you to send us another form with the additional or revised information.

We understand that you may receive multiple emails with the same request. However, each email is for a different facility you have registered in our Registration and Listing database, which means that it is very important that you respond with the unique data for each of your facilities. If the data are indeed identical, please state that in your response, and indicate for which facilities it is identical, so you do not have to copy unnecessarily.

If you manufacture more than one PPE device, please provide a separate response form for each medical device. We ask that you do not account for multiple products on the same form.

We appreciate your prompt reply to this request with as much information as you have currently. If you are able to obtain more information later, we ask for you to send us another form with the additional or revised information.

The yellow highlighted sections are of critical importance to us! We would appreciate you completing these sections within the next 2 hours. Please complete the additional sections within the next 12 hours.

Please send your responses directly to our email box at deviceshortages@fda.hhs.gov. If you would prefer to provide your responses by telephone, send your phone contact information to deviceshortages@fda.hhs.gov, and you will be contacted promptly.



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Thank you for helping to protect the public health.

Sincerely,

Shortages Team

Office of Product Evaluation and Quality

US FDA Center for Devices and Radiological Health

FIRM Information

Firm name:

FEI number:

Firm Location:

China

Taiwan

India

Other Asia Country

US

Outside US and Asia

Identify Country if not China, Taiwan, India, or
US_____

The firm DOES NOT make PPE.

The firm MAKES PPE that is/are (check all that apply)

GENERAL MASKS (not N95, not surgical non-N95).

SURGICAL MASKS (not N95).



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NON-SURGICAL N95 MASKS.

SURGICAL N95 MASKS.

ISOLATION GOWNS.

SURGICAL GOWNS.

NON-SURGICAL GOWNS

STERILE GLOVES.

NON-STERILE GLOVES.

OTHER PPE.

This firm makes other type(s) of PPE.

Describe: _____

The firm IS NOT adversely affected by nCoV

The firm IS adversely affected by nCoV.

Please describe

PRODUCT Information

Product name: (please provide a separate response form for each medical product)

END EMAIL FROM FDA

16. Is it possible to get temporary FDA registration?

No. But it is no longer required for the items talked about during the State of Emergency.

17. Is the FDA fee required for all three classes or just II and III?

Yes. The FDA facility registration fee is required for any company making any type of medical device.

18. Do we need to register with the FDA if we are just making or selling components?

No. Components are not regulated by the FDA.



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19. Are the QMS compliances needed for Class I devices?

They have just been exempted for the State of Emergency but will be required, with the exception of design controls, after the Emergency of over.

20. How can we get a copy of those template SOP's?

MEP has posted a list of the SOPs and forms required. I have provide the MEP a special cost for the templates if a company choses to get into the medical device industry longer than the embergency period.

21. Is there a SOP list for non 9001/13485 companies?

I have provided it to the National MEP and it is now posted.

22. What is involved in FDA registration? How do we do it? How much does it cost? How long does it take?

FDA registration and listing is an online process. It is renewed every October and lasts one year. Currently for 2020 the fee is \$5,236 and it goes up approximately 5% each year. It takes about a week if paying by credit card but that does not hold the company up from selling as a company "Normally" has 30 days to register AFTER it SELLS its first device.

23. Is the FDA website available to everyone?

Yes. www.fda.gov and go to the Medical Devices tab. One of the most informative is the Device Advice section at the following link:

<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>

24. What's the difference between the Classes and FDA codes?

FDA classes are the numeric I, II and III which designates the risk level the FDA believes is associated with the type of device. Class I is lowest risk. The 3 letter FDA code is give to each generic "TYPE" of device. For example, a surgical mask is a class II medical device with FDA code FXX.

25. Could you talk a bit more about 510(k) approval? What types of devices are under this, how long does it take, how much does it cost?

510(k)s are mostly for class II devices. It is a "me-too" type of marketing approval where the device is substantially equivalent to a device already on the market. The company will then send to the FDA information showing the FDA how their device is substantially equivalent to the predicate device already on the market. Each type of device is different and if you need additional information please contact us.

26. What's the difference between ISO 9001 and 13485? Do we need those?

You do not need ISO 9001 or ISO 13485 to product medical devices in the US. ISO 9001 is a general international quality system that can be implemented with any type of company. ISO 13485 is specifically for medical device companies. A company can be "compliant" with those



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standards on their own or they can have a 3rd party registrar come in routinely and certify the company to the standard(s).

27. Can we use expired gowns and surgical masks? Do they offer the protection needed?

These products were designed to serve as protective barriers and thus FDA believes they may still offer some protection even when they are used beyond the manufacturer's designated shelf life or expiration date. The user should visibly inspect the product prior to use and if there are concerns (such as degraded materials or visible tears) the product should be discarded.