

July 16, 2020

**Shreis Scalene Therapeutics LLC
11516 Darnestown Road
Gaithersburg, MD 20878 USA**

Attn: Meena Augustus

The Scalene Hypercharge Corona Canon (Shycocan) has been reviewed by the FDA via their Emergency Use Authorization (EUA) program for the COVID-19 public health emergency under P EUA201273.

The FDA has declined to issue an EUA for the Shycocan. As noted by the FDA:

“Please know that FDA is committed to doing everything possible to help combat the COVID-19 outbreak and appreciated your efforts to make your product(s) available. To help such efforts, FDA issued an immediately in effect guidance on March 29, 2020, “Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency”.^[1] The Scalene Hypercharge Corona Canon may fall under one of the policies set forth in this guidance, and be distributed without compliance with certain regulatory requirements as outlined in the guidance.”

The guidance that the FDA references allows certain products to be placed on the US market during the public health emergency under enforcement discretion related to requirements that would normally be required. Specifically, the FDA does not intend to object to the distribution and use of products within the scope of the guidance document, such as air purifiers, intended to be effective at killing the SARS-CoV-2 virus provided certain conditions are met. Once these conditions are met, it is Emergo’s understanding based on the FDA statements that this device may be put on the market during the public health emergency.

Briefly, in alignment with this guidance, the conditions to allow such distribution potentially relevant to the Shycocan are:

- If the device generates ozone, it does not generate more than the maximum acceptable level from 21 CFR 801.415
- Demonstration of reduction of SARS-CoV-2 or a representative virus, with a recommended 4 log₁₀ reduction

^[1] <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease>

- If intended for use in areas that have a sterile field or controlled air flow, a risk assessment to address turbulent air flow and/or potential site contamination
- Are not specifically intended to prevent hospital acquired infections (HAIs)
- Labeling that includes the following:
 - A clear description of the available data on the device's indications or functions related to SARS-CoV-2 such as:
 - Device performance
 - Potential risk
 - A statement that the product has not been FDA cleared for the intended indication.
 - A clear statement of the level of disinfection.
- The FDA provides additional labeling requirements for UV disinfecting devices, which although not technically requirements for the Shycocan, may be wise to consider. This labeling to consider is:
 - A caution that disinfection reduces the number of pathogens, but does not completely eliminate them.
 - A statement that the device is an adjunct to currently existing reprocessing practices and not a replacement or modification to such practices.
 - A statement regarding the time, distance, and maximum area over which the device has been evaluated for effectiveness.
 - An appropriate hazard warning label.
 - Procedures to follow if the device malfunctions or fails.

According to this guidance, the FDA is waiving the following standard requirements, where such devices do not create an undue risk in light of the public health emergency:

- Premarket submission per 21 CFR 807.81 and 21 CFR 814.39
- Registration and Listing per 21 CFR 807
- Unique Device Identification per 21 CFR 830 and 21 CFR 801.20

Note that standard requirements are not waived. An overview of these requirements include:

- A quality system in alignment with 21 CFR 820
 - This includes applicable procedures, and appropriate testing, including verification and validation testing, to ensure the safety and effectiveness of the device.
- Product labeling in alignment with 21 CFR 801 (except 21 CFR 801.20 Unique Device Identification)
- Medical device reporting and evaluation in alignment with 21 CFR 803
- Reporting of corrections and removals procedures in alignment with 21 CFR 806
- Postmarket surveillance procedures in alignment with 21 CFR 822



Emergo Global Consulting
2500 Bee Cave Road
Building 1, Suite 300
Austin, Texas 78746
UNITED STATES
+1 512 327 9997

Emergo recommends proceeding with a standard premarket submission to ensure that there is not a gap in the period when you can have the device on the market under the enforcement policy during the public health emergency and when the public health emergency is determined to be over.

If Shreis Scalene Therapeutics LLC is not familiar with your obligations as the legal Manufacturer or Specification Developer of a medical device under United States law, as detailed in the above referenced sections of the *Code of Federal Regulations (21 CFR)*, and feel that you need additional assistance in any one or more of these areas, Emergo can assist you in this regard. Since 1997, Emergo has helped thousands of clients implement (and maintain) their formal Quality Systems for compliance with the *Code of Federal Regulations*, and we would be happy to discuss this matter with you further. You can read more about Emergo's Medical Device Consulting Services for the United States on our website at <https://www.emergobyul.com/services/united-states>.

Shreis Scalene Therapeutics LLC can be inspected at any time by the FDA. FDA will inspect your Quality System to 21 CFR Part 820 to see if you are manufacturing your product(s) in compliance with these regulations. Remember that if the FDA finds any non-compliance(s) with the way Shreis Scalene Therapeutics LLC manufactures your device, they can issue you a FDA Form 483 of observations and/or a Warning Letter.

It was a pleasure working with you on this submission and all the best of luck on Scalene Hypercharge Corona Canon's (Shycocan) market introduction!

Call or email with any questions that you may have.

Kind regards,

Sarah Fitzgerald

EMERGO by UL | Senior Consultant, Quality and Regulatory Affairs

www.emergobyul.com



Emergo Global Consulting
2500 Bee Cave Road
Building 1, Suite 300
Austin, Texas 78746
UNITED STATES
+1 512 327 9997

Legal Notices

This document was prepared by Emergo exclusively for the client identified herein. This document does not carry any warranty or guarantee. Emergo does not assume or accept any duty, responsibility, or liability to any entity or individual other than the client. Emergo does not endorse or warrant the accuracy of any external sources cited herein, and Emergo cannot guarantee that any websites referenced herein retain their content and functionality.