Health Canada Santé Canada

Medical Devices Directorate
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July 21st, 2021

Authorization Reference No.:
321287

YI YU LAI
OWNER
INNOEN
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BRAMPTON, ON
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yylai@innoen.org

Notice of Intent

Interim Order to regulate certain ultraviolet radiation-emitting devices and ozone-generating devices under the *Pest Control Products Act*

Dear Yi Yu Lai:

We have reviewed the application that you submitted pursuant to the *Interim Order No. 2 Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19,* received on 24 September 2020, on behalf of **INNOEN** for the **COVID-19 Airborne Infection UV Quarantine Device**. Your application was placed on pause pending clarification regarding the appropriate regulatory pathway for these devices. The regulatory analysis was complex and required extensive collaboration between members of Health Canada's Medical Devices Directorate and the Pest Management Regulatory Agency. With the present letter, we wish to clarify the regulatory framework for ultraviolet radiation-emitting and ozone-generating devices in the context of the COVID-19 pandemic.

On June 7, 2021, the Minister of Health made an *Interim Order Respecting Ultraviolet Radiation-emitting Devices and Ozone-generating Devices*. The Interim Order brings certain ultraviolet radiation- emitting and ozone-generating devices under the *Pest Control Products Act* (PCPA). These devices are marketed to control or kill bacteria, viruses including SARS-CoV-2

(the coronavirus that causes COVID-19), and other microorganisms on surfaces, on objects, in water or in air.

Since the coming into force of the Interim Order under the PCPA, there are two pathways for authorizing ultraviolet radiation-emitting and ozone-generating devices, depending on their intended use:

1) Devices intended to disinfect or sterilize medical devices are regulated as medical devices under the *Interim Order No. 2 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19*
2) Devices intended to control, reduce, destroy, or inactive bacteria, viruses or other microorganisms that are human pathogens on surfaces, objects in water or in the air are regulated as pest control products under the PCPA.

Health Canada has published Questions and Answers to provide additional information on the scope of the Interim Order, the registration process and the conditions under which certain UV radiation-emitting devices would be exempt from registration (i.e., authorized).

To ensure expedited market access for your specific device, please respond to this letter with one of the following statements:

1) This device is intended to disinfect or sterilize medical devices. Please proceed with my application under the *Interim Order No. 2 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19*
2) This device is NOT intended to disinfect or sterilize medical devices. I hereby withdraw the application submitted under the *Interim Order No. 2 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19*.

If you need additional assistance to determine whether your product is intended to disinfect or sterilize medical devices, please contact hc.meddevices-instrumentsmed.sc@canada.ca with the subject line "Disinfection Device – Classification." Please attach the latest version of your product's labelling (e.g. instructions for use, box labels, promotional brochures) to the email.

Failure to provide a response within 10 days will result in your application being formally withdrawn. In such an instance, Health Canada will not follow-up with any additional communication regarding your application. Please refer to the IO guidance for additional information or contact me directly at (343) 549-2054 if you have questions regarding this letter.

Sincerely,

Colin Foster
Director
Bureau of Medical Device Licensing
Services