15 June 2020

Health Canada
Health Products and Food Branch
Medical Devices Directorate

Approval of the Baylis VFC-560 ventilator IO application

Baylis Medical

- Baylis Medical is a medical device company involved predominantly in the conception, development and commercialization of cardiology medical devices, and is located in Montreal, QC.
- Baylis Medical currently holds 24 Class II, Class III and Class IV medical device licences in Canada; first licence was issued on 2004-05-14.
- Baylis Medical is part of ISED's Made in Canada ventilator project, and is currently under contract with the Government of Canada to deliver 10,000 ventilators by Fall 2020 to help with COVID-19.

The Baylis V4C-560 Ventilator

- The VFC-560 is new and has not been approved in any jurisdiction to date.
- This ventilator is manufactured in Montreal, QC.
- Baylis was quoted on this intiative in this CBC article.
- Baylis Medical has worked closely with Medtronic in the development of the Baylis V4C-560 ventilator, which is closely based on the licensed Medtronic PB560 ventilator.
- "V4C" stands for "Ventilators for Canadians". Baylis has been using this expression frequently when referring to their ventilator.
- The ventilator is comprised of one internal battery and accessories including air inlet filters, exhalation blocks, oxygen connector, power cable, and a FiO2 measurement kit.
- Clinicians can use a variety of interfaces (i.e. mouthpiece, nasal masks or full-face masks; endotracheal tubes or tracheotomy tubes) to connect patients to the ventilator.
- The ventilator is suitable for use in institutional and home settings.
- Health Canada has determined that the Baylis VFC-560 ventilator meets the safety and effectiveness requirements to be eligible for authorization under the Interim Order for medical devices.

Its intended use

- The V4C-560 Ventilator is indicated for the continuous or intermittent mechanical ventilator support of patients weighing at least 11 lb (5 kg) who require mechanical ventilation.
- The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a doctor. It is essential to read, understand, and follow these instructions before using the V4C-560 Ventilator.
- The ventilator is specifically applicable for adult and pediatric patients who require general types of invasive or non-invasive ventilatory support, as prescribed by an attending doctor.

Next steps

- Health Canada will authorize the application on June 16, 2020.
- This information will be posted the next day on the List of authorized devices for COVID-19 other than testing devices.
- Anticipatory reactive media lines and this one-pager have been prepared.
- Minister Bains may announce this authorization in his PPE weekly update. This update will most likely take place on Wednesday (June 17).

Approved by
David Boudreau

Director General
Medical Devices Directorate