SAVe II+ Regulatory Summary

Under K131877, the SAVe II+ has a 510(k)-market clearance from the FDA for the following indications of use:

> The SAVe II™ is intended to provide short-term ventilatory support for adults during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF). The SAVe II™ is appropriate for adults that weigh at least 45 kg. It is intended to be used in pre-hospital, field hospitals, and transport environments.

Under Emergency Use Authorization 200336 (4/24/2020) and 200770 (5/7/2020), in response to the COVID-19 pandemic the SAVe II+ has been cleared by the FDA with the following indications of use:

> The SAVe II+ series are intended to provide ventilatory support for adults during CPR or when Positive Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF) or other situations where mechanical ventilation is needed. The SAVe II+ series are appropriate for adults that weigh at least 45 kg (99 lbs.). It is intended to be used in pre-hospital, field hospitals, outpatient environments, hospitals, ICU's, transport environments or any other healthcare environment requiring the use of a ventilator.

About the SAVe II+ Emergency Use Authorization (EUA 200700)

On February 4, 2020, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that involves the virus that causes COVID-19. The Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, during the COVID-19 pandemic.

On March 24, 2020, FDA authorized the emergency use of ventilators and other related technology subject to certain criteria established by FDA for safety, performance and labeling for emergency use in healthcare settings to treat patients during the COVID-19 pandemic.

On May 7, 2020, the FDA granted Emergency Use Authorization for the SAVe II+. The SAVe II+ embodies an improved electrical system, more powerful motor and upgraded software. The SAVe II+ achieves a maximum PEEP of 20 cmH2O and a maximum minute volume of 12.5 lpm. Subject to the conditions set forth in the EUA. Models M50016, and M50017 of the SAVe II+ have been added to the FDA's list of authorized devices contained in Appendix B of the EUA which can be viewed at: www.fda.gov/media/136528/download

The emergency use of the SAVe II+ Ventilator is consistent with the terms of the EUA, including the Scope of Authorization (for use in healthcare settings to treat patients during the COVID-19 pandemic emergency), Conditions of Authorization (inclusive of authorized labeling and manufacturer's processes for collecting and reporting adverse events etc.), and Criteria for Safety, Performance and Labeling (inclusive of conformance with standards and device specifications).

> FDA has determined that the SAVe II+ (M50016, M50017) model meet the criteria for safety, performance and labeling set forth in Section II and Appendix A of the EUA. As such, the specific SAVe II+ (M50016, M50017) model in your email are authorized for emergency use in healthcare settings to treat patients during the COVID-19 pandemic, subject to the conditions set forth in the EUA, and have been added to Appendix B of the EUA. The emergency use of the SAVe II+ (M50016, M50017) under this EUA must be consistent with the terms of the EUA, including the Scope of Authorization (Section II), Conditions of Authorization (Section IV), and Criteria for Safety, Performance and Labeling (Appendix A).