May 7, 2020

Emergency Use Authorization (EUA) SAVe II+

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) models 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).

Originally cleared Intended Use (as cleared in K131877):

The SAVe II™ series are 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 SAVeII™ series are appropriate for adults that weigh at least 45 kg. It is intended to be used in pre-hospital, field hospitals, and transport environments.

Intended Use (modified from K131877 under EUA 200336 and as amended):

The SAVe II series are intended to provide ventilatory support for adults during CPR or when PositivePressure 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. 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.

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