FAQ – FDA Emergency Use Authorization for Ventilators and Other Respiratory Devices

AAHomecare has compiled this FAQ regarding ventilators and other respiratory devices that have received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) during the COVID-19 public health emergency (PHE). Durable Medical Equipment (DME) suppliers should carefully review the information on the FDA web site to understand the scope of the EUA. As explained throughout the questions and answers, below, the devices that FDA lists are only authorized for ***emergency use in healthcare settings*** to treat patients during the COVID-19 pandemic. Use of the listed devices for other conditions and in other environments, such as obstructive sleep apnea (OSA) in a home setting, are not authorized and could result in FDA enforcement action.

1. **What is an EUA?**

An EUA is part of FDA's process to facilitate the availability and use of medical countermeasures, including ventilators, during PHEs, such as the current COVID-19 pandemic. Under an EUA, FDA may allow the use of ***unapproved*** medical products, or ***unapproved uses*** of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met. One criterion is the lack of adequate, approved, and available alternatives. Taking into consideration input from the FDA, manufacturers decide whether and when to submit an EUA request to FDA. Once submitted, FDA evaluates an EUA request and determines whether the relevant statutory criteria are met, taking into account the totality of the scientific evidence that is available to FDA.

2. **Why did FDA issue an EUA for certain respiratory devices?**

On March 24, 2020, the FDA issued an "umbrella EUA" to address the insufficient supply and availability of FDA-cleared ventilators for use in health care settings to treat patients during the PHE. A device is eligible for authorization under the umbrella EUA if: (1) it is not currently marketed in the U.S.; or (2) it is currently marketed in the U.S., but a modification is made to the device that would trigger the requirement for additional FDA review.

Therefore, devices authorized under the EUA have not undergone the normal and complete FDA regulatory review that is necessary to clear a device. Instead, during the PHE the FDA is allowing the use of the devices under specific conditions of authorization that are enumerated in the EUA.

Link to FDA EUA for Ventilators

3. **Which devices are authorized under the EUA?**

FDA provides a list of authorized devices on its website in Appendix B, "Authorized Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories for use in healthcare settings by patients during the COVID-19 pandemic." Users can input key words into the search box at the top of the list to find a manufacturer, model, product code, or any other word in Appendix B.

Link to Appendix B, "Authorized Ventilators, Ventilator Tubing Connectors and Ventilator Accessories

4. **What information is included in Appendix B?**

Appendix B on FDA's website includes the following information:

a. Date of Authorization
b. Manufacturer
c. Product Name
d. Device Description,
e. Intended Use, and
f. FDA Assigned Product Code

Many of our members have inquired about the "intended use" that appears when the entry for a device is expanded (using the + button). This information may be from the manufacturer of the device; however, it is not FDA's statement of the intended use under the EUA.

5. **How do I determine the authorized uses for the devices listed in Appendix B under the EUA?**

The EUA authorizes the ventilators, ventilator tubing connectors, and ventilator accessories listed in Appendix B for ***emergency use in healthcare settings to treat patients during the COVID-19 pandemic***. The emergency use of authorized ventilators, ventilator tubing connectors, and ventilator accessories ***must be consistent with, and may not exceed, the terms of the EUA***.

This document is provided as an informational service by AAHomecare; it does not constitute legal advice. We recommend that you consult the FDA and your regulatory counsel if you have additional questions.

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