

Accession Number: S0399 **ECRI Priority:** High **Published:** 04/29/2020
Channel: Devices **FDA:** Not Specified **Last Updated:** 04/29/2020

[COVID-19] Ventilators on FDA Emergency Use Authorization List: Hospitals Should Seek Clarity on Post-EUA Status Before Purchasing [ECRI Exclusive Special Report]

Problem

1. FDA has authorized the sale of a [wide variety of ventilatory support devices](#) during the COVID-19 pandemic under the Emergency Use Authorization (EUA).
2. The status of these devices once the EUA is terminated may be ambiguous.
 1. Some vendors have explicitly stated that their authorized devices will no longer be usable when the EUA is terminated and have advised hospitals to destroy or otherwise dispose of the devices.
 2. Some vendors have told hospitals that they intend to pursue 510(k) clearance for the devices.
 3. Many vendors have not made their intentions clear to potential buyers.
3. Facilities could unknowingly purchase devices that can only be legally used for the duration of the COVID-19 pandemic.
4. Using a device that has not been cleared or approved by FDA outside the special exemption provided by the EUA could expose hospitals to liability and/or action by accreditors or payers.

ECRI Recommendations:

1. Talk to vendors of the authorized devices to clearly understand their intentions for those devices once the emergency is declared over and the EUA is terminated.
2. If possible, work directly with the device supplier rather than third parties or distributors. The supplier is more likely to know the restrictions on EUA devices and to be able to speak to future plans for such devices.
3. Refer to the [FDA list of authorized devices](#). The Device Description and Intended Use information for each device can help provide context for the type of device and for the vendor's post-EUA intentions.
4. Assume that all authorized devices will revert to their pre-EUA state when the EUA is terminated.
 1. FDA-cleared devices with EUA labelling changes will revert to their pre-EUA labelling.
 2. FDA-cleared devices with EUA modifications will be usable if the modifications are reverted or removed.
 3. Devices that are not FDA-cleared will not be usable until or unless they receive clearance.
5. Consider your current and future needs before purchasing any device from the EUA list.
 1. [Click Here](#) for a table describing purchasing decisions for various device types.

Background:

1. On March 24, 2020, FDA issued an EUA in response to concerns that hospitals would not have enough ventilators to treat the expected surge of COVID-19 patients.
2. FDA also issued detailed guidance that spelled out the scope of the EUA, the types of devices they expected to authorize, and the information requested by the vendors.
3. The EUA is effective until such time that FDA determines the COVID-19 emergency is over.
4. FDA Guidance on EUAs states that authorized devices must be disposed of at the termination of the EUA. Any future use of such a device is subject to regulations that cover investigational use.
5. Some vendors have indicated that they intend to pursue 510(k) clearance of their authorized devices. However, the timing of 510(k) clearances is uncertain. There will likely be a window between the end of the EUA and the eventual clearance where hospitals will be unable to use these devices.

References & Source Documents:

1. Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities>

Geographic Region(s)

U.S.

Suggested Distribution

Anesthesia, Clinical/Biomedical Engineering, Critical Care, Pulmonology/Respiratory Therapy, Risk Management/Continuous Quality Improvement, Materials Management

Comment

- This alert is a living document and may be updated when ECRI receives additional information.