March 28, 2023

FDA Confirms No Current Expiration Date for LUISA Ventilator EUA

Overview

The LUISA® home ventilation system is currently being sold in the United States under authority of the U.S. Food and Drug Administration (FDA) under its Emergency Use Authorization (EUA) declared under section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA). In December 2021, the FDA issued draft guidance providing a transition plan for all medical devices such as the LUISA which had been authorized for sale under EUAs. On March 24, 2023, the FDA issued two final guidance documents to assist with transition plans for both EUA's and other cleared devices, in response to public comments to the December 2021 drafts.[1]

PHE Expiration

It has been widely reported that the Department of Health and Human Services (HHS) announced that, based on current COVID-19 trends, HHS is planning for the federal Public Health Emergency (PHE) for COVID-19, declared under Section 319 of the Public Health Service Act (PHS Act), to expire on May 11, 2023. In the updated Guidance, the FDA clarifies that the Section 319 declaration will be subject to a 180-day transition period expiring on November 7, 2023.[2]

However, because the LUISA was issued under an EUA declaration under FDCA section 564 and not a PHE declaration, **HHS's action has no effect on the LUISA**. In the second Guidance issued on March 24,[3] the FDA reaffirmed that an EUA declaration under section 564 of the FDCA "is distinct from, and is not dependent on, a declaration by the HHS Secretary of a PHE under section 319 of the PHS Act." To the contrary, an EUA issued under section 564 of the FDCA Act "remains in effect for the duration of the relevant EUA declaration."

At this time, **the FDA has not set a date for expiration of the EUA for any medical devices**, including for the LUISA. The new Guidance confirms that if at some date in the future the FDA decides to set a date, it will publish this date in the Federal Register to provide 180 days' advance notice for the effective date of termination. Even if the FDA gives 180 days' notice, EUA devices may continue to be distributed after the effective date of termination if a marketing submission (such as a (510(k) premarket notification) is administratively complete (i.e., includes all of the information necessary for FDA to conduct a substantive review) prior to the effective date of termination. A 510(k) premarket notification for the LUISA has been submitted and is currently pending before the FDA.

Guidance for Modified Devices during COVID-19 Pandemic

During the COVID-19 Pandemic, FDA guidance allowed manufacturers certain flexibility to make changes on certain FDA-cleared products. In particular, the FDA permitted manufacturers to make some changes to ventilator products in response to supply chain demands, as well as flexibility in implementing remote monitoring functions for these

[1] FDA Issues Final Guidances to Assist with Transition Plans for COVID-19-Related Medical Devices, available at https://www.fda.gov/medical-devices/medical-devices-news-and-events/fda-issues-final-guidances-assist-transition-plans-covid-19-related-medical-devices.

[2] Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease.

[3] Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease.

devices to avoid unnecessary risks to healthcare professionals[4]. The Guidance **was not** intended to allow manufacturers to implement new clinical features or operating modes which were not previously cleared.

Because the FDA policy permitting such modifications remains in effect only for the duration of the PHE, the recent announcement of the PHE's expiration will affect modified ventilation products, and therefore modified products will be subject to the transition period guidelines described above, with an anticipated transition date of November 7, 2023. Note that the LUISA does not fall under this guidance and will not be affected by the PHE expiration.

Contact

For more information, go to www.movair.com or contact a Movair representative at info@movair.com or by calling (512) 326-3244.

[4] Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus.