FOLEY HOAG LLP

FDA Alert

FDA Issues Emergency Use Authorizations for Additional Medical Devices in Response to COVID-19

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On Friday, April 10, 2020, the Food and Drug Administration (FDA) announced that it has issued two additional Emergency Use Authorizations (EUA) in response to the coronavirus pandemic: one for a device that is used to decontaminate respirators for re-use by health care workers and another for a blood purification system to treat certain patients afflicted with the disease.

- The first EUA authorizes the use of specified sterilization systems made by STERIS Corporation to decontaminate compatible N95 or N95-equivalent respirators using vaporized hydrogen peroxide.The EUA allows for these sterilization systems to be used in decontaminating single-user respirators for re-use by health care workers to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of the N95 resulting from the pandemic. The systems are capable of processing 10 respirators at a time through a process that takes approximately 28 minutes to complete, for a maximum of 10 decontamination cycles per respirator. FDA issued an EUA for a different decontamination system (the Battelle Decontamination System) for use in decontaminating compatible respirators for reuse by health care workers on March 28, 2020.
- The second EUA authorizes the use of a blood purification system to treat patients who are at least 18-years old with confirmed coronavirus disease and have been admitted to the intensive care unit (ICU) with confirmed or imminent respiratory failure.The EUA was issued to Terumo BCT Inc. and Marker Therapeutics AG for their Spectra Optia Apherises System and Depuro D2000 Absorption Cartridge devices. FDA has determined that the use of the system may effectively separate plasma from whole blood and that the cartridge may remove various pro-inflammatory cytokines from the plasma, which may provide some clinical benefit for these patients.

FDA subsequently issued a similar EUA on April 11 to Advanced Sterilization Products, Inc. for the emergency use of select models of its STERRAD vaporized hydrogen peroxide sterilization systems to decontaminate compatible N95 and N95-equivalent respirators for up to two decontamination cycles per respirator.

FDA has the authority to issue EUAs when circumstances exist that justify the authorization of emergency use of an unapproved medical product or an unapproved use of an approved medical product for certain emergency situations.

In addition to the EAUs described above, FDA has issued EAUs covering devices such as ventilators and personal respiratory protective devices as well as in vitro diagnostic tests and high complexity molecular-based laboratory developed tests for use in the detection and/or diagnosis of the novel coronavirus in response to the pandemic.

Foley Hoag has formed a firm-wide, multi-disciplinary task force dedicated to client matters related to the novel coronavirus (COVID-19). For more guidance on your COVID-19 issues, visit our Resource Page or contact your Foley Hoag attorney.

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