

Noxilizer announces FDA 510(k) clearance of a medical device sterilized using a nitrogen dioxide process -- accelerates pharmaceutical, biotech and medical device submissions globally

June 1, 2016 (Baltimore, MD) Noxilizer, Inc., the company advancing the NO₂-based sterilization process for pharmaceutical, biotech and medical device manufacturers, is pleased to announce a 510(k) clearance from the US Food and Drug Administration (FDA) for a medical device terminally sterilized using Noxilizer's nitrogen dioxide sterilization process.

"Receiving a FDA clearance marks a pivotal milestone for Noxilizer," says Lawrence Bruder, Noxilizer CEO. "This clearance confirms that nitrogen dioxide sterilization is another option for companies – especially for those products, like prefilled syringes, drug-delivery systems and medical devices -- that face challenges with ethylene oxide, gamma radiation or other conventional sterilization methods."

"The FDA spent considerable time and due diligence evaluating the nitrogen dioxide sterilization process, mechanism of action and validation approach," adds Bruder.

"Based on work already underway, Noxilizer is very excited that this approval is the first of many more."

Nitrogen dioxide gas sterilization is unique because it sterilizes at ultra-low temperature (10-30°C) and functions with or without vacuum and humidity. All of these are important factors for the growing number of biotech drugs and temperature-sensitive medical devices. Noxilizer's nitrogen dioxide sterilization also allows companies to safely bring sterilization back in house, greatly reducing process time, leading to turnaround times of 2-3 days and operational cost savings of 50% or more.

With this clearance, Noxilizer has established a pathway to 510(k) approvals for nitrogen dioxide sterilized devices in the industrial medical device market.

About Noxilizer, Inc.:

Noxilizer, Inc. provides an ultra-low temperature nitrogen dioxide process that offers many benefits over traditional sterilization methods. Noxilizer sells sterilization and biodecontamination equipment to pharmaceutical, biotech and medical device manufacturers and also offers contract sterilization services at its Baltimore, MD facilities. Noxilizer's expert microbiology and material compatibility team is ready to partner to solve sterilization challenges through every phase of the process. Noxilizer, Inc. has offices in the US, United Kingdom and Japan. For more information, please visit: www.noxilizer.com.

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