REVOX®
Sterilization Solutions
by Cantel Medical

Regulatory pathways for VPA sterilization

REVOX™ sterilization process and the medical device regulatory landscape

Q: If I switch to REVOX™ sterilization from my current sterilization method, will I need new regulatory clearance (FDA, CE, etc) of my medical device?

A: Yes, because REVOX™ sterilization is classified as a "novel" sterilization method, it is likely that a new clearance will be required. For example, one of our clients, OsteoSymbionics™, manufactures a class II implantable medical device (Clear Shield™ cranial implant) that already had FDA 510(k) clearance. But to begin manufacturing it using the REVOX™ sterilization method, the company had to reapply for clearance to ensure the full process for its medical device met all regulatory requirements, including those associated with the sterilization process.

Q: Does the REVOX™ sterilization system itself require regulatory clearance?

A: The REVOX system is not required to have a separate clearance by the largest medical health regulatory bodies, such as the FDA (US), TGA (Australia), CFDA (China), and various country agencies within the European Union (EU). This is because REVOX is not a medical device itself; it is an industrial sterilizer. Only those sterilization systems that are specifically designed for use in hospitals and other health care settings require their own, separate "medical device" clearances.

While some sterilizers that were designed and FDA 510(k) cleared for use in health care settings are also being used for industrial applications, that is irrelevant to the regulatory requirements for industrial use. The controlling FDA guidance document specifies that "sterilizers intended for use in hospital facilities require 510(k)s. Industrial sterilizers do not require 510(k)s." Most global medical device regulatory authorities also follow this precedent.

Q: If not FDA clearance, what international regulations and standards must the REVOX™ sterilization process comply with?

A: Most countries' regulatory bodies look to global standard organizations such as AAMI, ANSI, and ISO, which base their specific guidance on scientific, clinical, and practical expert information. The ISO 14937 standard provides overarching, yet highly specific recommendations for sterilization of medical devices.

At present, there are no ISO standards specific to the vaporized peracetic acid (VPA) process that REVOX uses, but following ISO 14937 ensures broad adherence to sterilization requirements. Because the REVOX™ sterilization process may be new to regulatory authorities and/or notified bodies, it's important that they understand that the REVOX system is an industrial sterilizer that is not being used in a health care setting. Despite the existence of such global standards, we recognize that each country's regulatory bodies may have their own additional requirements, and we stand ready to assist manufacturers in meeting those specific, individual demands.

Q: How does the FDA classify the REVOX™ sterilization process when used in the medical device manufacturing process?

A: In the United States, the controlling FDA guidance document (released in early 2016) classifies sterilization methods according to three categories. REVOX VPA is currently categorized as a "Novel Sterilization" method. While the sterilization techniques in this category do not yet possess a history of comprehensive FDA evaluations, REVOX VPA has been approved for use as the sterilization method on a FDA 510(k) Class II implantable device. This represents the first FDA approved device with the use of a novel sterilization method in more than 20 years. To date, REVOX® PA, the liquid peracetic acid used by the REVOX machines has received two FDA 510(k) clearances as a sterilant.

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Q: Will clearance of my device using REVOX VPA take longer than other sterilization methods?

A: The REVOX team helped OsteoSymbionics™ gain its FDA 510(k) clearance within nine months after submission by closely partnering with the client to meticulously follow the FDA's guidance for a novel sterilization method. This involved the REVOX team providing four major tranches of information, along with applicable published scientific literature:

1. A comprehensive description of the sterilization process
2. The method used to validate the sterilization cycle (e.g., the half-cycle method)
3. The validation protocol
4. The sterilization validation data

As a June 2014 FDA presentation to the Parenteral Drug Association explained, getting all the details of 510(k) submission right is paramount to speeding a medical device to market. "If validated appropriately and clearly described in the application," the FDA presentation explained, "new methods are approved usually on the first review cycle."

How will the REVOX team help us navigate the regulatory process?

As a medical device manufacturer, Cantel Medical has a strong track record of regulatory compliance and a team of experienced regulatory affairs professionals who work with our clients to find the best path forward to ensure all regulatory submissions are thorough and comprehensive. Regulatory considerations are typically among the first topics of discussion upon initial engagement with prospective clients. We encourage our clients to discuss their concerns with our team of experts.

Your innovations are unique. Let us help you navigate the regulatory process on an individual basis to ensure compliance and eliminate delays in getting to market.

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