INNOVATIVE STERILIZATION TECHNOLOGIES, LLC DISPUTES FDA WARNING LETTER CONCLUSIONS

ONE TRAY® rigid sterilization container maintains a cleared storage period.

Dayton, OH August 22, 2019 -- Innovative Sterilization Technologies, LLC ("IST" or the "Company"), developer of the ONE TRAY® rigid sterilization container, is announcing today in this release that the Company is in receipt of a Warning Letter from the U.S. Food and Drug Administration (FDA), dated March 20, 2019 but posted publicly by the Agency on August 20, 2019. FDA's Warning Letter alleges a number of differences between the ONE TRAY®'s 510(k) clearance and the uses for which the device is currently marketed. IST has been inspected by FDA multiple times over the last six years. In every instance, IST was transparent and cooperative, fully addressed FDA questions, and resolved inspectional observations. Throughout the warning letter, FDA has made multiple statements that are false and/or inaccurate. For example, the FDA states "*During FDA's November 2015 inspection, FDA investigators notified your firm that these claims represented new intended uses and that you needed to submit a premarket submission which would allow FDA to evaluate the safety and effectiveness of your device for these uses*." This statement is patently false as the FDA never notified IST during ANY of the four inspections that a new 510(k) submission would be required. IST appealed FDA's issuance of the Warning Letter on March 28, 2019, due to this and other inaccuracies in the factual statements and assumptions contained in the Warning Letter. FDA denied IST's appeal to withdraw the Warning Letter on August 15, 2019.

To date, IST has not received and is otherwise not aware of any reportable adverse events related to the retention of residual moisture within the device following a sterilization cycle. Based on this undisputed fact and the company's extensive testing data, IST is confident that continued use of the ONE TRAY within its cleared and marketed indications for use does not pose a risk of harm to patients.

IST firmly maintains that its currently marketed indications for use are within the scope of FDA's original clearance and that FDA's current position reflects a change in the Agency's original position upon which clearance was based. Specifically, the 510(k) notice for the ONE TRAY® device (K052567) included a validated storage period following processing without a dry time and with retention of residual moisture within the device. The ONE TRAY® 510(k) summary posted on FDA's website also specifically lists "shelf life" testing of the device and the sterile instruments it holds without a dry time based on performance testing relied upon for clearance (http://www.accessdata.fda.gov/cdrh_docs/pdf5/K052567.pdf). Subsequent to clearance, IST extended the shelf life in accordance with FDA guidance regarding modifications to cleared devices. FDA investigators reviewed these extensions to shelf life during every FDA inspection with no issues identified.

In discussions with FDA prior to publication of the Warning Letter, IST also communicated to the Agency that the ONE TRAY® was cleared to process a twenty five pound (25 lb.) gross weight load (single container plus contents) in a steam pre-vacuum cycle at 132°C for 4 minutes exposure time; or in a steam gravity cycle at 132°C for 34 minutes exposure time. IST did not validate the ONE TRAY® for a flash sterilization cycle nor did IST seek clearance for such use. Thus, none of IST's cleared sterilization parameters are the kind of rapid, short term cycles that FDA has subsequently cleared as flash sterilization or "IUSS" cycles where device and instrument storage are precluded. Moreover, the definition of IUSS was not even established until 2011. IST's cleared uses utilize cycles that are consistently cleared by FDA when the containers and the instruments they hold are intended for storage, or "terminal sterilization" as currently defined by the Center for Medicare and Medicaid Services and industry.

“We followed FDA guidance as written. FDA’s actions and post hoc interpretation of the clearance that it issued to IST in 2006 are arbitrary and capricious and we are willing to do whatever it takes to make this right,” said Scott Cohen, Chief Executive Officer. “We are confident that the ONE TRAY® clearance under which our product has been marketed for many years included a validated and FDA cleared storage claim. We also maintain that the company’s actions in extending the ONE TRAY®’s cleared storage period following FDA guidance documents for medical device shelf life and the same test methods used to establish the cleared shelf life period were entirely appropriate.”

IST reiterates its confidence in the ONE TRAY consistent with its clearance. The Company is pursuing additional appeals to the FDA Commissioner’s Office through the Office of Scientific Integrity, while also preparing for legal action against the FDA, if necessary.

Source: Innovative Sterilization Technologies, LLC.

Contact
Walt Oko
VP Quality and Regulatory Affairs
7625 Paragon, Rd, Suite A
Dayton, OH 45459
937.619.0138