FOR IMMEDIATE RELEASE

FDA Warning Letter against Innovative Sterilization Technologies (IST) is closed - ONE TRAY®'s 2006 clearance stands.

DAYTON, OHIO January 9, 2023 — Innovative Sterilization Technologies (IST)/**ONE TRAY®** in Dayton, Ohio has announced that a Warning Letter issued in March 2019 by the U.S. Food and Drug Administration (FDA) has been closed. The FDA, as part of the warning letter review and correspondence, confirmed **ONE TRAY®**'s clearance contained a validated **48-hour storage period** and has agreed that the company may use the specific language in the company's labeling consistent with the indications for use cleared in 2006. IST also attempted to remove the antiquated term "FLASH" without success, however, IST has agreed with the FDA regarding the uses for which the device may be labeled/marketed and commercialized. During the warning letter closure process, the FDA stated that "a key distinction of Immediate Use Steam Sterilization (IUSS) is that it cannot and should not be stored."

Dave Billman, Chief Operations Officer stated, "We are pleased to announce a resolution with the FDA on this matter. **ONE TRAY®** is the solution that drives efficiency for healthcare facilities. We are happy our storage claim, which has been there from the beginning, has been acknowledged by the FDA."

Removal of the warning letter

The warning letter closure follows the discussions surrounding sterilization terminology and acknowledges the storage of the **ONE TRAY®** rigid sterilization container. FDA conclusions in the warning letter, which the company believes to include factual inaccuracies, does not take into consideration the following: current industry sterilization terminology, the scope of the **ONE TRAY®** 510k clearance, FDA's long standing policy and guidance with respect to when to obtain clearance for device modifications, nor the years of interactions between the two parties (2014-current).

IST has been factual, and transparent in all FDA interactions since the commercialization of **ONE TRAY®**. In addition, management of IST has maintained that the company's marketing has been within the scope of the industry definitions and followed FDA's guidance of the product in accordance with published FDA guidance documents. We are accordingly pleased to have resolved this long-standing compliance concern with the FDA.

Where do we go from here?

Since the commercialization of **ONE TRAY®** in 2013, there have been more than 5 million uses with no reported medical device reporting (MDR) events. IST's products and processes have been repeatedly reviewed by the FDA, and all inspection observations have been addressed. Innovation comes with a lot of uphill battles, and IST has consistently taken on, and will continue to take on confidently, education supported by facts. Closure of the Warning Letter by the FDA shows compliance of IST and acknowledgment of the previously stated cleared validated 48-hour storage period.

If you have any questions regarding the closure of the **ONE TRAY®** Warning Letter, please contact the company at 937.619.0138, visit onetray.com/fdawarningletter and send us a message, or email us at info@onetray.com. Follow the **ONE TRAY®** IFU for use.

About IST - Innovative Sterilization Technologies (IST) was founded in 2013 with the goal of delivering products that ensure effective reprocessing efficiencies and economic savings in medical device sterilization. Our mission is to provide the highest quality sterilization container products supported by years of reliable service to our customers. We are committed to educating our industry on how new technology affects current practices and guidelines to help create an environment that benefits not only the user but supports our customers in their effort to provide One Standard of Care.

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