



November 24, 2017

SciCan Ltd.
Teresa Boyce
Director of Regulatory Affairs
1440 Don Mills Road
Toronto, M3B 3P9 Ca

Re: K172292

Trade/Device Name: SALUS® - Hygiene Instrument Reprocessing Container
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: October 27, 2017
Received: October 31, 2017

Dear Teresa Boyce:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use510(k) Number (if known)
k172292Device Name
SALUS® - Hygiene Instrument Reprocessing Container

Indications for Use (Describe)

The SALUS® - Hygiene is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The SALUS® - Hygiene is a reusable instrument reprocessing container intended to enclose and organize instruments that are designed to withstand steam sterilization and to maintain sterility of the reusable instruments during storage. The SALUS - Hygiene is suitable for use in dynamic air removal steam sterilizers.

Please refer the chart below for validated sterilization cycles.

Steam Sterilizer Type	Cycle	Sterilization Temperature -0/+6°F (-0/+3°C)	Exposure Time	Recommended Drying Time	Load Type	Maximum Instrument Load Per Container
Dynamic-air-removal (pre-vacuum)	Wrapped	270°F (132°C)	4 minutes	16 minutes	Solid Hygiene Instruments & Lumen Hygiene Instruments (Ø .028" [0.7mm] x L 3.35" [85 mm], Qty. 1)	0.487lb (221g)
Dynamic-air-removal (steam-flush, pressure-pulse, SFPP)	Wrapped	270°F (132°C)	4 minutes	30 minutes		0.478lb (217g)
Dynamic-air-removal (pre-vacuum)	Wrapped	273°F (134°C)	4 minutes	30 minutes		0.473lb (215g)

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)☒ Over-The-Counter Use (21 CFR 801 Subpart C)**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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