March 31, 2022

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

Re: K214057
Trade/Device Name: STATIM 6000B Vacuum Autoclave
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: January 5, 2022
Received: January 6, 2022

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray, III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214057

Device Name
STATIM 6000B VACUUM AUTOCLAVE

Indications for Use *(Describe)*
The STATIM 6000B are dynamic air removal (pre-vacuum) table-top steam sterilizers that are intended for use by a healthcare provider to sterilize medical products by means of pressurized steam.

The STATIM 6000B are suitable for the sterilization of dental and medical instruments that are validated to be sterilized by steam. The STATIM 6000B has not been designed to sterilize liquid loads, biomedical waste or materials not compatible with steam sterilization. The processing of such loads may result in incomplete sterilization and/or damage to the autoclave.

A table describing the STATIM 6000B programs, cycle times, temperatures and dry times is available on the next page.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PROGRAM NAME	STERILIZATION TEMPERATURE AND TIME	DRYING TIME (min) (*)	CYCLE TIME MAX. LOAD 120V (min.) (***)	CYCLE TIME MAX. LOAD 240V (min.) (***)	MAXIMUM LOAD (***)	LOAD DESCRIPTION (**)
SOLID UNWRAPPED	132°C / 270°F 4 minutes	1	19.3min	14.5min	1kg	Unwrapped solid instruments (mirrors, explorers), hinged instruments (hemostats) on trays
HOLLOW UNWRAPPED	132°C / 270°F 4 minutes	1	20.5min	27.7min	1kg	Unwrapped Solid instruments, handpieces, hollow or lumen instruments (mirrors, explorers), hinged instruments (hemostats) on trays
SOLID WRAPPED	132°C / 270°F 4 minutes	11	33min	29.3min	2.6kg	Double-wrapped IMS cassettes with solid instruments or single-pouched solid instruments on a tray or pouch rack
HOLLOW WRAPPED	132°C / 270°F 4 minutes	11	31.1min	17.3min	2.6kg	Wrapped Solid Instruments, handpieces, hollow or lumen instruments (mirrors, explorers), hinged instruments (hemostats) on trays
RUBBER & PLASTIC WRAPPED	121°C / 250°F 20 minutes	5 **,***	48.2min	44.1min	1kg	Wrapped or Unwrapped solid or hollow instruments constructed of metal, rubber and plastic.
TEXTILES/POROUS WRAPPED	132°C / 270°F 4 minutes	11min **,***	37min	28.5min	1.4kg	Unwrapped or wrapped textiles

(*) Default drying time, but the drying time can be manually increased.
(**) If the material is sterilized “unwrapped” the sterilized material shall be used immediately after sterilization (the cycle shall be considered as an Immediate Use Steam Sterilization (IUSS) cycle).
(***) Depending on the type of load, it may be necessary to optimize drying using the extra drying function.