DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Teresa Boyce
Director of Regulatory Affairs
SciCan Limited
1440 Don Mills Road
Toronto, Ontario
CANADA M3B 3P9

JUL 10 2012

Re: K112872
Trade/Device Name: STAT*IM* 2000/5000 G4 Cassette Autoclave
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: June 7, 2012
Received: June 11, 2012

Dear Ms. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K112872

Device Name: **STAT*IM* 2000/5000 G4 Cassette Autoclave**

Indications for Use:

The STAT*IM* 2000/5000 G4 Cassette Autoclaves are steam flush pressure pulse dynamic air removal steam autoclaves designed for the reprocessing of reusable medical and dental instruments to achieve successful sterilization in a clinical setting. They utilize saturated steam at high pressures in order to attain an effective kill of infectious bio-organisms.

The units are intended to sterilize heat and moisture stable medical and dental instruments (including handpieces) which are commonly found in medical and dental offices, hospitals, clinics, and other facilities. The instruments must be suitable for steam sterilization at 134°C (275°F) or 121 °C (250°F). The STAT*IM* 2000/5000 G4 Cassette Autoclaves are only intended for heat stable instruments.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: SciCan Ltd. K112872
STAT*IM* 2000 / 5000 G4 510(k)

INDICATIONS FOR USE – Page 2 of 3

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The sterilization cycles as to established times, temperatures and indicated uses for the STAT*/M* 2000 G4 Cassette Autoclave are as follows:

CYCLE	TEMPERATURE	STERILIZATION / DRYING TIME	MAX LOAD	INTENDED USE
UNWRAPPED (for Immediate Use)	135°C (275°F)	3.5 min. / 60 min.	1.0 kg (2.2 lbs)	Solid metal instruments, hinged metal instruments, dental[1] and phaco[2] handpieces, with drying.
WRAPPED	135°C (275°F)	10 min. / 60 min.	1.0 kg (2.2 lbs)	Solid, hollow (including dental[1] and phaco[2] handpieces) & hinged metal instruments wrapped in paper/paper or paper/plastic pouches that are cleared by FDA for the claimed cycles, with drying.
RUBBER & PLASTICS	121°C (250°F).	15 min. / 60 min.	0.4 kg (0.9 lbs)	Instruments of rubber & plastic construction (exceptions are listed in the Operator's Manual) with drying

The lumen specifications are as follows:

[1]Dental Handpieces: 7 handpieces within a 1 kg load

[2]Phaco Handpieces: 2 handpieces, 2 lumens per handpiece, where the lumens have a minimum inner diameter of 1.5 mm (0.06") and a maximum length of 150 mm (6") or a minimum inner diameter of 2 mm (0.08") and maximum length of 190 mm (7.5")

Prescription Use _____ AND/OR Over-The-Counter Use ✓
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510(k) Number: SciCan Ltd. K112872

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510(k) Number: K112872

The sterilization cycles as to established times, temperatures and indicated uses for the STAT*IM* 5000 G4 Cassette Autoclave are as follows:

CYCLE	TEMPERATURE	STERILIZATION / DRYING TIME	MAX LOAD	INTENDED USE
UNWRAPPED (for Immediate Use)	132°C (270°F)	3.5 min. / 60 min.	0.5 kg (1.1 lbs)	Solid metal instruments, hinged metal instruments with drying.
WRAPPED	132°C (270°F)	6 min. / 60 min.	1.5 kg (3.3 lbs)	Solid, hollow (including dental[1] and phaco[2] handpieces) & hinged metal instruments wrapped in paper/paper or paper/plastic pouches that are cleared by FDA for the claimed cycles, with drying.
RUBBER & PLASTICS	121°C (250°F)	35 min. / 60 min.	0.4 kg (0.9 lbs)	Instruments of rubber & plastic construction (exceptions are listed in the Operator's Manual) with drying.
HEAVY DUTY UNWRAPPED (for Immediate Use)	132°C (270°F)	6 min. / 60 min.	1.5 kg (3.3 lbs)	Solid metal instruments, hinged metal instruments and dental[1] and phaco[2] handpieces with drying. The extended cassette must be used for the processing of longer instruments such as autoclavable rigid endoscopes[3] in this cycle.

The lumen specifications are as follows:

[1]Dental Handpieces: 8 handpieces within a 1.5 kg load

[2]Phaco Handpieces: 5 handpieces, 2 lumens per handpiece, where the lumens have a minimum inner diameter of 1.5 mm (0.06") and a maximum length of 150 mm (6") or a minimum inner diameter of 2 mm (0.08") and maximum length of 190 mm (7.5")

[3]Rigid Endoscopes: 3 scopes, 1 lumen per scope, where the lumens have a minimum inner diameter of 1 mm (0.04") and a maximum length of 490 mm (19")

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