K072466

Summary of Safety & Effectiveness Information

510(k) Summary:

Submitted by:

SciCan Ltd.
1440 Don Mills Road
Toronto, Ontario Canada
M3B 3P9

DEC 1 9 2007

Contact Person:

Teresa Boyce – Senior Regulatory Affairs Specialist
(416) 446-2783

Date of Preparation: August 31, 2007

Name of Device: STAT*IM* 7000 Cassette Autoclave

Predicate Device: STAT*IM* 5000 Cassette Autoclave
510(k) K962179

Description of Device:

The STAT*IM* 7000 Cassette Autoclave is a pressure pulse steam autoclave designed to process medical and dental instruments to achieve successful sterilization. The unit utilizes saturated steam at high pressures in order to attain an effective kill of infectious bio-organisms and prevent cross infection. Instruments are placed within the provided cassette, the cassette is placed within the armature, the cycle parameters are selected and the start button depressed. The unit is then fully automatic for the complete sterilizing cycle.

Intended use:

The unit is intended to sterilize heat and moisture stable medical and dental instruments (including dental handpieces) within a hospital or clinical setting such as medical and/or dental surgeries. The instruments processed within the STAT*IM* 7000 Cassette Autoclave must be suitable for steam sterilization at 134°C (273°F) or 121°C (250°F).

The sterilization cycles as to established times, temperatures and indicated uses for the STAT*IM* 7000 Cassette Autoclave are as follows:

CYCLE	TEMPERATURE	TIME	INTENDED USE
UNWRAPPED	134°C (273°F)	3.5 min.	Solid instruments, hinged instruments, dental handpieces, with heated drying
WRAPPED	134°C (273°F)	3.5 min.	Solid, hollow (including dental handpieces) & hinged instruments wrapped in paper/paper or paper/plastic pouches or paper sterilization wrap, with improved drying performance
RUBBER & PLASTICS	121°C (250°F).	30 min.	Instruments of rubber & plastic construction (exceptions are listed in the Operator's Manual) with heated drying

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2007

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

Re: K072466
Trade/Device Name: STATIM 7000 Cassette Autoclave
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: November 28, 2007
Received: November 30, 2007

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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:

Device Name: **STAT*IM* 7000 Cassette Autoclave**

Indications for Use: The STAT*IM* 7000 Cassette Autoclave is a pressure pulse steam autoclave designed to process medical and dental instruments to achieve successful sterilization in a clinical setting. It utilizes saturated steam at high pressures in order to attain an effective kill of infectious bio-organisms and prevent cross infection.

The unit is intended to sterilize heat and moisture stable medical and dental instruments (including dental handpieces) that are commonly found in medical and dental offices, hospitals, clinics, and other facilities. The instruments must be suitable for steam sterilization at 134°C (273°F) or 121 °C (250°F). The STAT*IM* 7000 Cassette Autoclave is not intended nor recommended for the sterilization of liquids, cloths, textiles, biomedical waste and certain rubber and plastic materials specified in the Operator's Manual.

The sterilization cycles as to established times, temperatures and indicated uses for the STAT*IM* 7000 Cassette Autoclave are as follows:

CYCLE	TEMPERATURE	NO. OF PURGES	STERILIZATION TIME	INTENDED USE
UNWRAPPED	134°C (273°F)	3	3.5 min.	Solid instruments, hinged instruments, dental handpieces, with drying
WRAPPED	134°C (273°F)	6	3.5 min.	Solid, hollow (including dental handpieces) & hinged instruments wrapped in paper/paper or paper/plastic pouches or paper sterilization wrap, with improved drying performance
RUBBER & PLASTICS	121°C (250°F).	3	30 min.	Instruments of rubber & plastic construction (exceptions are listed in the Operator's Manual) with drying

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072466