AUG 0 8 2002

Summary of Safety & Effectiveness Information

K021064

510(k) Summary:

Submitted by:	SciCan, Division of Lux & Zwingenberger Ltd. 1440 Don Mills Road Toronto, Ontario Canada M3B 3P9
Contact Person:	Brenda Murphy - Regulatory Affairs Manager (416) 446-2797
Date of Preparation:	March 27, 2002
Name of Device:	QUANTIM 16 Autoclave
Predicate Device:	Midmark M-11 Ultraclave Steam Sterilizer 510(k) 990189

Description of Device:

The QUANTIM 16 Autoclave is a gravity 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 simply placed within the autoclave on the trays or carriers provided, the doors are closed, the cycle parameters 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 QUANTIM 16 Autoclave must be suitable for steam sterilization at 132°C (270°F).

The sterilization cycles as to established times, temperatures and indicated uses for the QUANTIM 16 Autoclave are as follows:

CYCLE	TEMPERATURE	TIME	INTENDED USE
UNWRAPPED	132°C (270°F)	3 min.	Flash cycle for solid instruments, hinged instruments, dental handpieces, with drying
WRAPPED	132°C (270°F)	15 min.	Solid & hinged instruments, dental handpieces, with drying
PACKS	121°C (250°F).	30 min.	Textiles & wrapped surgical packs with drying
LIQUIDS	121°C (250°F).	30 min.	Liquids suitable for sterilization in open top flasks, with drying (not intended for direct patient contact)

Technological Characteristics Compared to the Predicate Device:

The QUANTIM 16 Autoclave uses similar technological characteristics of the predicate device. In this respect, the intended use, operating principle, general materials of construction, and controls are similar for both devices. Both units use saturated steam at high pressures and temperatures to achieve the complete destruction of micro-organisms.

The Midmark M-11 Sterilizer generates the steam inside the sterilization chamber by use of an electric heating element.

In an innovative process, the QUANTIM 16 actually generates the steam in a small boiler located beneath the main chamber and which then quickly fills the chamber with saturated steam. This process serves to reduce chamber build-up and extend the chamber life significantly.

The QUANTIM 16 Autoclave and the Midmark M-11 Sterilizer both have four (4) programmed cycles as described in the above table. At the end of every sterilization cycle, the QUANTIM 16 unit automatically begins a vacuum drying cycle of approximately 30 minutes. While the load is drying, the door may be opened at any time by pressing the button. This action terminates the dry cycle and automatically opens the door when it is safe.

In comparison, the Midmark-11 unit exhausts upon completion of the sterilization cycle, and the door automatically opens slightly to allow air drying of the instruments. However, the goods may also be removed at any time during the drying cycle.

Performance Data:

The actual performance levels in relation to sterility claims of the QUANTIM 16 Autoclave were demonstrated through laboratory testing using the commonly recognized test organism, *Bacillus stearothermophilus*. Using the validated culture medium and validated spores, ½ cycle testing, total kill end point testing, and simulated use testing with dental handpieces and medical and dental instruments were performed as outlined in the FDA's March 1993, *Guidance of Premarket Notification [510(k)] Submission for Sterilizers Intended for Use in Health Care Facilities*

Test Results

Testing which was conducted under generally recognized and accepted laboratory practices by subcontracted parties was designed to be complete and challenging in relation to the performance and safety of the Quantim 16 unit for its intended use.

SciCan considers that the testing results demonstrated the Quantim 16 Autoclave to be safe and effective and to be substantially equivalent to the predicate device.

The testing results indicated that no live spores could be detected on any of the test instruments following simulated use testing. It was determined that the Quantim 16 unit met the objective of sterilization of the defined load(s) –including dental hand pieces - to the acceptable SAL.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Brenda Murphy
Manager, Regulatory Affairs
SciCan, Division of Lux & Zwingenberger
1440 Don Mills Road
Toronto, Ontario
Canada M3B 3P9

Re: K021064
Trade/Device Name: Quantim 16 Autoclave
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: June 28, 2002
Received: July 3, 2002

Dear Ms. Murphy:

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.

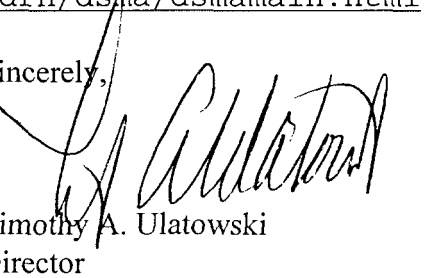
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely,



Timothy A. Ulatowski
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: **K021064**

Device Name: **QUANTIM 16 Table-top Autoclave**

Indications for use: The QUANTIM 16 tabletop autoclave is a gravity 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) which are commonly found in medical and dental offices, hospitals, clinics, and other facilities. The instruments must be suitable for steam sterilization at 132°C (270°F). Two additional cycles are also specified for (i) the sterilization of textiles and wrapped surgical packs and (ii) liquid loads contained in open top glass flasks. However, the QUANTIM 16 Table-top Autoclave is not intended nor recommended for sterilization of liquids intended for direct patient contact.

The sterilization cycles as to established time, temperatures, load configurations, drying time and indicated uses for the QUANTIM 16 Table-top Autoclave are as follows:

CYCLE	STERILIZATION TEMPERATURE	MAXIMUM LOAD	STERILIZATION TIME	DRYING TIME	INTENDED USE
Unwrapped	132°C (270°F)	2kg (4.4lbs)	3 min.	30 min.	Flash cycle for solid and hinged instruments, dental handpieces
Wrapped	132°C (270°F)	1kg (2.2lbs)	15 min.	30 min.	Solid and hinged instruments, dental handpieces
Packs	121°C (250°F)	1kg (2.2lbs)	30 min.	30 min.	Textiles and wrapped surgical packs
Liquids	121°C (250°F)	2kg (4.4lbs)	30 min.	N/A (no drying phase)	Liquids suitable for sterilization in open top flasks (not intended for direct patient contact)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021064