510(k) Summary
for
iMax 9.5 DS Sterilizer

SEP - 5 2006

1. SPONSOR

Dental X srl
Via Marzotto 11
36031 Dueville
Vicenza
ITALY

Contact Person: Dr. Marco Nesti
Telephone: 0039-0444-367411

Date Prepared: August 17, 2006

2. DEVICE NAME

Proprietary Name: iMax 9.5 DS Sterilizer
Common/Usual Name: Steam sterilizer
Classification Name: Steam sterilizer

3. PREDICATE DEVICES

- Delta Steam Sterilizer (K945117)
- Midmark M9 UltraClave (K023348)

4. DEVICE DESCRIPTION

The iMax 9.5 DS Sterilizer is a gravity table-top steam sterilizer. The iMax 9.5 DS Sterilizer is provided with a diaphragm compressor and HEPA filter that circulates filtered air in the sterilization chamber during the drying phase.

5. INTENDED USE

The iMax 9.5 DS Sterilizer is a gravity table-top steam sterilizer intended for heat and moisture resistant medical and dental (including complex lumened devices such as dental handpieces) instruments and cloth packs for sterilization in healthcare facilities.

Three pre-programmed sterilization cycles are provided with the iMax 9.5 DS Sterilizer (see table below).

Cycle	Temperature (°C)	Pressure (bar)	Exposure Time (min.)	Drying Time (min.)	Maximum Load (kg)
Unwrapped instruments*	134	2.14 – 2.21	4	6	4.0
Wrapped instruments**	134	2.14 – 2.21	20	20	4.0
Packs	121	1.10 – 1.17	30	20	1.5

* Not indicated for the processing of complex instruments (i.e. containing lumens, hinges, mated surfaces, etc.)

**Dental handpieces can be processed in the Wrapped instruments cycle only

The sterilizer is not intended to sterilize patient-contacting liquids.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Both the proposed and predicate devices are gravity-fed microprocessor-controlled table top steam sterilizers consisting of a sterilization chamber with a water storage and transport system, heating elements for steam generation, and a valve system for exhausting air and steam for the chamber. Differences in the technical features between the proposed and predicate devices are limited to minor differences in chamber volume, dimensions, etc.

7. PERFORMANCE TESTING

Software and performance testing was conducted to determine the safety and effectiveness of the proposed iMax 9.5 DS Sterilizer for its' intended use. The testing included electrical safety testing, electromagnetic compatibility testing and physical testing to ensure that all design requirements were fulfilled. Biological testing was conducted to verify the sterilization efficacy of the preprogrammed process parameters. Additional testing was conducted using both laboratory-inoculated and clinically contaminated dental handpieces to confirm that the iMax 9.5 Sterilizers could be used for the sterilization of complex lumened devices. The

results confirm that the iMax 9.5 DS Sterilizer is safe and effective for the sterilization of steam-compatible medical and dental instruments, including dental handpieces.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dental X SRL
C/O Cynthia J.M. Nolte
Medical Device Consultant, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

SEP - 5 2006

Re: K052532
Trade/Device Name: iMAX DS 9.5 Sterilizers
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: August 17, 2006
Received: August 17, 2006

Dear Ms. Nolte:

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.

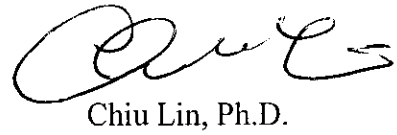
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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

510(k) Number (if known): K052532

Device Name: iMax 9.5 DS Sterilizer

Indications for Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use X (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sign-Off)
of Anesthesiology, General Hospital,
Control, Dental Devices
Number: K052532 9/1/04