MAR - 1 2004

K033764

8. SMDA Summary of Safety and Effectiveness – "510(k) Summary"

A. Submitter Information

SATELEC
Z.I. du Phare, BP 216
17, Avenue Gustave Eiffel
33708 Merignac Cedex
FRANCE

Telephone: 011 33 5 5634 0607

Contact Person: Pascal Dupeyron
Regulatory Affairs

Date Prepared: December 1, 2003

B. Device Identification

Common/Usual Name: Piezoelectric Ultrasound Scaling Generator
Proprietary Name: SP NEWTRON Module

C. Identification of Predicate Devices

The SP NEWTRON module is substantially equivalent to its predicate devices, SP 4055 and SP 4055 LUX Modules (K972026) from SATELEC previously cleared and currently marketed.

D. Device Description

The SP NEWTRON is a multi-purpose Piezoelectric Ultrasonic Scaling Generator sub-assembly which is an upgraded generation of the SP 4055 and SP 4055 LUX Modules from SATELEC that received 510(k) clearance for dental applications (K972026) on July 9, 1997. The SP NEWTRON maintains all the functions and the main components of the SP 4055 and SP 4055 LUX Modules. It is a stand-alone sub-assembly manufactured by SATELEC, all with the same components and materials used in the manufacture of the original SP 4055 and SP 4055 LUX Modules products, which can be used in standard dental units. The indented use, technical performance, and clinical indications are identical to those of their predicate devices, the SP 4055 and SP 4055 LUX Modules (K972026).

The SP NEWTRON module is a multi-purpose ultrasonic generator to be marketed as a modular sub-assembly to OEM manufacturers of dental units. Each module is shipped with three standard tips, (# 1, # 2 and # 10P) but can be used with a variety of optional tips with up to 70 different models. According to clinical indications, the SP NEWTRON offers 3 setting ranges:

- scaling, prosthesis conservative/restorative,
- ultrasonic endodontic treatment, and
- ultrasonic periodontal treatment.

As the ultrasonic waves are produced by piezoelectricity, the SP NEWTRON hand pieces give off very little heat, making it possible for surgeons to perform both periodontal work (sub-gingival work at low power, where the absence of overheating is vital), as well as loosening (requiring high power, but without the unpleasant side-effect of a hot hand piece).

The SP NEWTRON, similar to its predicate devices, SP 4055 and SP 4055 LUX Modules (K972026) from SATELEC, operates from the action of cavitation, following the efficient propagation of ultrasound signals in a frequency spectrum comprised between 28 and 36 kHz.

The electronic automatic control system has the capability to adjust power instantaneously in function of the resistance encountered by the tip, and varies with hand-piece and tip frequency so as to optimize power output.

E. Substantial Equivalence:

The technical characteristics of the SP NEWTRON are almost identical to those of the SATELEC SP 4055 and SP 4055 LUX Modules. Differences that exists between the above systems relating to technical specifications, materials, physical appearance, and control systems are minor and do not affect the relative safety or effectiveness of the SP NEWTRON relative to the SP 4055 and SP 4055 LUX Modules.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2004

Mr. Pascal Dupeyron
Regulatory Affairs
SATELEC
Z.I. Du Phare, BP 216
17, Avenue Gustave Eiffel
33708 Merignac Cedex,
FRANCE

Re: K033764
Trade/Device Name: SP NEWTRON Module
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: December 1, 2003
Received: December 2, 2003

Dear Mr. Dupeyron:

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.

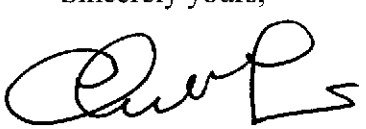
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.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

K033764

Indications for Use

510(k) Number (if known): K033764

Device Name: SP Newtron Module

Indications For Use:

Scaling
- Interdental junction treatment
- Tooth neck and subgingival treatment
- Treatment of large deposits
- Treatment of coating and tobacco stains
- Interproximal treatment
- Prosthesis conservative/restorative:
  - Inlay/onlay condensation
  - Amalgam plugging
  - Loosening prostheses (bridge, crown, post, pivot...)

Endodontia:
- Canal preparation
- Canal cleaning
- Canal filling
- Gutta percha condensation
- Treatment resumption
- Retro surgery
- Micro retro surgery
- Surface smoothing after burring

Periodontia:
- Root planing
- Initial therapy
- Treatment of periodontal pockets
- Treatment of furcations
- Maintenance therapy
- Implant maintenance

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

Kai Mealey for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033764