APR 2 0 2005

K050895

9. 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: March 15, 2005

B. Device Identification

Common/Usual Name: Piezoelectric Ultrasound Scaling Generator
Proprietary Name: SUPRASSON P5 NEWTRON

C. Identification of Predicate Devices

The SUPRASSON P5 NEWTRON is substantially equivalent to its predicate devices, SUPRASSON P5 Booster (K961158) and SP NEWTRON Module (K0033764) from SATELEC previously cleared and currently marketed.

D. Device Description

The SUPRASSON P5 NEWTRON is a multi-purpose piezoelectric ultrasonic generator: it is an upgraded generation of the SUPRASSON P5 Booster Piezoelectric Ultrasonic Scaling Generators from SATELEC which received 510(k) clearance for dental applications (K961158) on May 23, 1996, including the technology of the SP NEWTRON module which received 510(k) clearance for dental applications (K033764) on March 1, 2004. The SUPRASSON P5 NEWTRON maintains all the functions and the key components of the SUPRASSON P5 Booster and SP NEWTRON Module; it is a stand-alone device manufactured by SATELEC, all with the same components and materials used in the manufacture of the original SUPRASSON P5 Booster and SP NEWTRON module. The intended use, technical performance, and clinical indications are equivalent to those of their predicate devices, the SUPRASSON P5 Booster (K961158) and SP NEWTRON Module (K033764).

The SUPRASSON P5 NEWTRON consists of three main components: the ultrasonic handpiece instrument, the control panel case, and the footswitch.

The ultrasonic handpiece instrument (cleared by FDA - K033764) is held in the physician's hand, but it can also be stored in the holder located onto the case. The handpiece is connected to the control panel case via a fixed electrical cable connection.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 20 2005

SATELEC
C/O Mr. Ned Devine
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K050895
Trade/Device Name: Suprasson P5 Newtron
Regulation Number: 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: April 8, 2005
Received: April 8, 2005

Dear Mr. Devine:

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

Indication for Use

510(k) Number (if known): K050895

Device Name: **SUPRASSON P5 NEWTRON**

Indications For Use:

Periodontics
Endodontics
Scaling
Prosthesis

Please refer to the attached listing for a complete description.

Prescription Use ___X___ 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: K050895

INDICATIONS FOR USE
SATELEC SUPRASSON P5 NEWTRON

Periodontics:

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

Endodontics:

- Canal preparation
- Canal cleaning
- Canal filling
- Gutta percha condensation
- Treatment resumption
- Retro Surgery
- Micro Retro Surgery

Scaling (prophylaxis):

- 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...)