K071424

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

A. Submitter Information

AUG 24 2007

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Contact Person: Steve Salesky
SATELEC
c/o Acteon, Inc.
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Date Prepared: May 11, 2007

B. Device Identification

Common Usual Name: Ultrasonic scaler

Proprietary Name: Pmax Newtron XS

C. Identification of Predicate Device

Device	Applicant	510(k) No.	Date Cleared
Suprasson® P5 Newtron	Satelec	K050895	April 20, 2005

The Satelec Pmax Newtron XS is substantially equivalent to the predicate device by Satelec, the Suprasson® P5 Newtron (K050895) previously cleared by the FDA and currently marketed.

D. Device Description

The Pmax Newtron XS is an ultrasonic scaler for use by qualified dental practitioners in the four conventional dental applications of prophylaxis, periodontics, endodontics, and prosthesis.

The Pmax Newtron XS device uses piezoelectric ultrasound technology to generate mechanical microvibrations for ultrasonic scaling, with minimal trauma to soft tissue.

The Pmax Newtron XS™ function offers four utilization modes at pre-set ultrasound power settings. The power of the ultrasound can be finely adjusted

by the user.

Range	Ultrasound power	Procedure
Green	Low	Periodontics mainly
Yellow	Medium	Endodontics mainly
Blue	High	Prophylaxis mainly
Orange	Very high	Prosthesis or Specific treatment modalities

Liquid irrigation is provided by two 300 mL self-contained solution tanks and the Newtron LED handpiece provides light and air functions. The light is provided by a light ring consisting of high-performance light-emitting diodes (LED) in the handpiece and air is delivered to the handpiece for air irrigation through connection of the control unit to the user's dental surgery's medical quality filtered air distribution system.

E. Substantial Equivalence

The Pmax Newtron XS and the predicate device, Suprasson® P5 Newtron (K050895) are both ultrasonic scalers for use in conventional dentistry by qualified dental practitioners. Differences that exist between the devices relating to technical specifications, performances and intended use are minor and do not affect the safety and effectiveness of the Pmax Newtron XS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SATELEC
C/O Mr. Steve Salesky
Quality Manager
Acteon, Incorporated
124 Gaither Drive, Suite 140
Mount Laurel, New Jersey 08054

AUG 24 2007

Re: K071424
Trade/Device Name: Pmax Newtron XS
Regulation Number: 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: August 13, 2007
Received: August 15, 2007

Dear Mr. Salesky:

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.

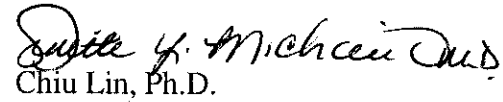
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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Indications for Use

510(k) Number: _____

Device Name: **Pmax Newtron XS**

Indications for Use:

The Pmax Newtron XS is intended for use by qualified dental practitioners in the following dental applications:

Periodontics
Endodontics
Scaling
Prosthesis

Please refer to the attached listing for a detailed description.

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

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INDICATIONS FOR USE
Pmax Newtron XS

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...)