K091331

510(k) Pre-Market Notification for Satelec PIEZOTOME 2

DEC 11 2009

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

A. Submitter Information

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SATELEC
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Date Prepared: May 1st, 2009

B. Device Identification

Common Usual Name: Bone cutting instrument and accessories

Proprietary Name: PIEZOTOME 2

C. Identification of the Predicate Device

Device	Applicant	510(k) No.	Date Cleared
PIEZOTOME	Satelec	K060274	May 1, 2006

The Satelec PIEZOTOME 2 is substantially equivalent to the predicate device by Satelec, the PIEZOTOME (K060274) previously cleared by the FDA and currently marketed.

D. Indications for Use: The intended use of the Satelec PIEZOTOME 2 is to supply utilities to and serve as a base for dental tools such as ultrasonic scaler,

bone cutting instrument and accessories for use by qualified dental practitioners in periodontics, endodontics, scaling, prosthesis and oral surgery.

E. Device Description

The Satelec PIEZOTOME 2 is a dental operative unit that supplies utilities to and serves as a base for dental tools such as ultrasonic scaler, bone cutting instrument and accessories for use by qualified dental practitioners in periodontics, endodontics, scaling, prosthesis and oral surgery.

F Substantial Equivalence

The PIEZOTOME 2 and the predicate device, PIEZOTOME (K060274) are both dental operative units that supplies utilities to and serves as a base for dental tools such as ultrasonic scaler, bone cutting instrument and accessories for use by qualified dental practitioners in periodontics, endodontics, scaling, prosthesis and oral surgery. Differences that exist between the devices relating to technical specification, performances and intended use are minor and do not affect the safety and effectiveness of the PIEZOTOME 2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 11 2009

SATELEC
C/O Mr. Rick Rosati
Quality Manager
ACTEON, Incorporated
124 Gaither Drive, Suite 140
Mount Laurel, New Jersey 08054

Re: K091331
Trade/Device Name: Piezotome 2
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZI
Dated: November 23, 2009
Received: November 24, 2009

Dear Mr. Rosati:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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: K091331

Device Name: **PIEZOTOME 2**

Indications for Use:

The intended use of the Satelec PIEZOTOME 2 is to supply utilities to and serve as a base for dental tools such as ultrasonic scaler, bone cutting instrument and accessories for use by qualified dental practitioners in periodontics, endodontics, scaling, prosthesis and oral surgery.

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)

Kai Mahy for MSP

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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