K060274
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9. SMDA Summary of Safety and Effectiveness – "510(k) Summary"

A. Submitter Information

MAY 1 2006

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Contact Person: Steve Salesky
SATELEC
c/o Acteon, Inc.
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Mt. Laurel, NJ 08054
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E-mail: steve.salesky@us.acteongroup.com

Date Prepared: January 30, 2006

B. Device Identification

Common Usual Name: Bone Cutting Instrument and Accessories

Proprietary Name: Piezotome™

C. Identification of Predicate Device

Device	Applicant	510(k) No.	Date Cleared
Piezosurgery®	Piezosurgery Srl	K043408	June 8, 2005

The Satelec Piezotome™ is substantially equivalent to the predicate device by Piezosurgery Srl, the Piezosurgery® (K043408) previously cleared by the FDA and currently marketed.

D. Device Description

The Piezotome™ is a bone cutting instrument intended for use in oral surgery.

The Piezotome™ device uses piezoelectric ultrasound technology to generate mechanical microvibrations for bone cutting, with minimal trauma to soft tissue. The device is supplied with bone surgery, sinus lift, and ligament cutting tips for use in dental surgery, including osteotomy, osteoplasty, periodontal surgery, and implantology.

This device is fitted with two handpiece cord connectors. Depending on the application, the practitioner may connect two handpieces at the same time.

The Piezotome™ function offers four utilization modes at pre-set ultrasound power settings.

The user regulates the flow rate of the irrigation fluid.

The practitioner controls the device using a keyboard and a multi-function footswitch.

The irrigation fluid flow rate and the ultrasound power are monitored on a screen. For enhanced efficacy, the last settings are memorized by the machine.

E. Substantial Equivalence

The Piezotome™ and the predicate device, Piezosurgery® (K043408), are both bone cutting instruments for use in oral surgery. 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 Piezotome™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 2006

SATELEC
C/O Mr. Steve Salesky
Regulatory Affairs
ACTEON, Incorporated
130 Gaither Drive, Suite 100
Mount Laurel, New Jersey 08054

Re: K060274
Trade/Device Name: Piezotome™
Regulation Number: 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZI
Dated: January 30, 2006
Received: February 2, 2006

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.

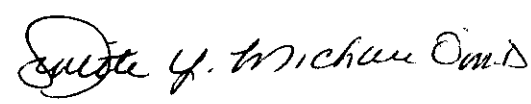
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number: K060274

Device Name: **Piezotome™**

Indications for Use:

The Piezotome™ device is a bone cutting instrument intended for use in 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)

Susan Runner

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K060274