510(k) Pre-Market Notification for Satelec PIEZOELECTRIC SYSTEM

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

A. Submitter Information

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APR 2 8 2010

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SATELEC
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Email: rick.rosati@us.acteongroup.com

B. Device Identification

Common Usual Name:	Sonic surgical instrument and accessories/attachments
Proprietary Name:	PIEZOELECTRIC SYSTEM
Classification:	Class II device (per 21 CFR § 888.4580)

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C. Identification of the Predicate Device

	Predicate 1	Predicate 2	Predicate 3
Device name	Piezosurgery® Medical Device	Electric Pen Drive	IMPLANT CENTER 2
Sponsor	Mectron Spa	Synthes	SATELEC - ACTEON
K number	K083284	K043310	K091252

D. Device Description

The Satelec PIEZOELECTRIC SYSTEM is an operative unit that consists of a console, a power cord, a foot pedal, a wrench and a handpiece. The PIEZOELECTRIC SYSTEM device uses piezoelectric ultrasound technology to generate mechanical microvibrations for bone cutting, with minimal trauma to soft tissue.

A variety of attachments will be available for the Piezoelectric System for cutting bone, bone substitutes, osteotomy, osteoplasty, decorticating, drilling, shaping and smoothing of bones and teeth in a variety of surgical procedures. These attachments will be available "Sterile" –Single Use only (do not re-use).

E. Indications for Use

The Piezoelectric System distributed by Synthes USA is an ultrasonic surgical system consisting of handpieces and associated tips for cutting bone and bone substitutes. The system can be used for osteotomy, osteoplasty, decorticating, drilling, shaping, and smoothing of bones and teeth in a variety of surgical procedures, including general orthopaedic, otolaryngological, maxillofacial, oral, hand, foot, neurosurgical, spine, and plastic/reconstructive surgery.

F. Substantial Equivalence

Information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Satelec
% Acteon, Inc.
Mr. Rick Rosati
124 Gaither Drive, Suite 140
Mt. Laurel, New Jersey 08054

APR 2 8 2010

Re: K100410
Trade/Device Name: Piezoelectric System
Regulation Number: 21 CFR 888.4580
Regulation Name: Sonic surgical instrument and accessories/attachments
Regulatory Class: Class II
Product Code: JDX, DZI, ERL, HBE, HWE
Dated: April 15, 2010
Received: April 16, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K100410

Device Name: **Piezoelectric System**

Indications for Use:

The Piezoelectric System, distributed by Synthes, is an ultrasonic surgical system consisting of handpieces and associated tips, for cutting bone, bone substitutes and metal. The system can be used for osteotomy, osteoplasty, decorticating, drilling, shaping, and smoothing of bones and teeth, in a variety of surgical procedures, including general orthopaedic, otolaryngological, maxillofacial, oral, hand, foot, neurosurgical spine, and plastic/reconstructive surgery.

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100410