PIEZOSURGERY®

Piezosurgery s.r.l.
Registered Office:
Molo Ponte Morosini 41/7 - 16126 Genoa, Italy
Headquarter:
Via Portobello, 12 - 16039 Sestri Levante, Italy
Tel:+39 0185 450863, Fax:+39 0185 42799
E-mail: piezosurgery@piezosurgery.com

APR - 8 2009

K083284

510(k) Summary in accordance with 21 CFR 807.92(c)

Device Name:	Piezosurgery Medical
Type of 510(k) submission:	Traditional
Date of Submission:	31 October 2008
Manufacturer:	Mectron Spa Via Loreto, 15, Carasco, GE 16042, Italy
FDA Registration Number:	3003933619
510(k) Owner:	Piezosurgery SRL Registered Office: Molo Ponte Morosini 41/7 -16126 GE Italy Headquarters: Via Portobello, 12 – 16039 Sestri Levante GE Italy
510(k) Contact:	Roger Gray Director, Global Regulatory Affairs Donawa Consulting Piazza Albania, 10, 00153 Rome, Italy Tel: +39 06 578 2665 Fax: +39 06 574 3786
Trade Name:	Piezosurgery Medical
Common Name:	Bone cutting instrument and accessories
Classification Regulation:	888.4580: Sonic surgical instrument and accessories/attachments
Identification:	A sonic surgical instrument is a hand-held device with various accessories or attachments, such as a cutting tip that vibrates at high frequencies, and is intended for medical purposes to cut bone or other materials, such as acrylic.
Class:	Class II
Product Codes:	HWE, DZI, ERL, HBE and JDX

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Predicate Devices:

Predicate device 1	Predicate device 2	Predicate device 3
Synthes Electric Pen Drive (EPD) System	**Linvatec E9000 System**	**Piezosurgery (oral use)**
Synthes (USA)	Linvatec Corporation	Mectron SPA
1690 Russell Road Paoli, PA 19301 USA	11311 Concept Boulevard Largo, FL 33773-4908 USA	Via Loreto, 15/A 16042 Carasco (GE) ITALY
K043310	K990524	K043408

Device Description:

The Piezosurgery® Medical device is an ultrasonic surgical system consisting of a central console with two integral peristaltic irrigation pumps, and two detachable handpieces. Each handpiece is connected to the console electrically, and each is also connected to one of the irrigation pumps via an irrigation tubing kit. The handpieces contain the ultrasonic transducers. A separate electrically-operated footswitch is provided with the device, which also attaches to the central console. The irrigation tubing kits and insert tips are supplied sterile and are intended for single-use. A range of optionally available handpiece tips provides the surgeon with a wide variety of options for drilling, cutting and sawing.

The console has a touch-screen display and contains general control system circuits and two ultrasonic generators which drive the handpiece functions. The irrigation tubing kit is fed with physiological saline solution during the surgical procedure from saline bags (not supplied) which hang from drip stands that attach to the rear of the central console.

The user may activate either of the two handpieces by the selection from the LCD touch-screen and by pressing the footswitch.

Intended Use:

The Piezosurgery MEDICAL is an ultrasonic surgical system consisting of handpieces and associated tips for cutting bone, osteotomy, osteoplasty and drilling in variety of surgical procedures, including but not limited to otolaryngological, oral/maxillofacial, hand, foot, neurosurgical, spine, and plastic/reconstructive surgery. It may also be used with endoscopic visual assistance to perform the above listed procedures.

Technological Characteristics:

The desired surgical effect is obtained by using an ultrasonic frequency of resonance modulated in amplitude with low frequency bursts according to the bone quality program selected by the operator. The integral Piezosurgery® electronic generator performs automatic tuning of the working frequency, optimizing the efficiency of the piezoelectric transducer in the handpiece.

This feature makes it possible to produce a "hammering effect" of the insert tip, resulting in a cutting action.

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Performance Data:

Depending on the object bone type, the user can select four cutting modalities. The flow rate of physiological saline irrigation solution is user-adjustable on five levels, and the user may also set the power output from a choice of seven levels.

Conclusion:

Based on the information contained within this submission, it is concluded that the Piezosurgery Medical device is substantially equivalent to the predicate devices already in interstate commerce within the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2009

Piezosurgery SRL
% Donawa Consulting
Mr. Roger Gray
Piazza Albania, 10 · 00153 Rome
Italy

Re: K083284
Trade/Device Name: Piezosurgery Medical device
Regulation Number: 21 CFR 888.4580
Regulation Name: Sonic surgical instrument and accessories/attachments
Regulatory Class: II
Product Code: JDX, HWE, DZI, ERL, HBE
Dated: Mach 24, 2009
Received: March 31, 2009

Dear Mr. Gray:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Indications for Use

510(k) Number (if known): Not known K083284

Device Name: Piezosurgery Medical device

Indications for Use: The Piezosurgery MEDICAL is an ultrasonic surgical system consisting of handpieces and associated tips for cutting bone, osteotomy, osteoplasty and drilling in variety of surgical procedures, including but not limited to otolaryngological, oral/maxillofacial, hand, foot, neurosurgical, spine, and plastic/reconstructive surgery. It may also be used with endoscopic visual assistance to perform the above listed procedures.

Prescription Use (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 General, Restorative, and Neurological Devices

510(k) Number K083284