JUN 8 - 2005

Piezosurgery 510(k) Summary of Safety and Effectiveness
in accordance with 21 CFR 807.92 (c)

K number: K043408

1. Submitter's information:

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2. Contact person:

Maria E. Donawa, M.D.
Donawa Consulting
P.zza Albania, 10
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3. Date summary prepared: June 6, 2005

4. Device name and classification:

- **a. Trade/device name:** Piezosurgery®
- **b. Classification name:** Bone Cutting Instrument and Accessories (per 21 CFR section 872.4120)
- **c. Classification panel:** Dental
- **d. Regulatory class:** Class II
- **e. Product code:** DZI

5. Device description:
The Piezosurgery® device uses piezoelectric ultrasonic technology to generate mechanical microvibrations for bone cutting, with minimal trauma to soft tissue. The device is supplied with sharp, smoothing and blunt insert tips for use in oral surgery, including implantology, periodontal surgery and surgical orthodontics.

6. Intended use:
The Piezosurgery device is a bone cutting instrument intended for use in oral surgery.

7. Predicate device:
Micro-motor system MD20 Nouvag (K042434)

8. Substantial equivalence comparison:
Technical, clinical and histologic comparisons presented in this submission support a finding of substantial equivalence between Piezosurgery and other bone cutting devices already in commercial distribution in the US. In addition, this technology has been shown to allow precise osteotomies with minimal risk of tissue heating and osteonecrosis damage.

9. Performance evaluations:

Performance and safety evaluations were based on clinical and histologic data on the incision characteristics, cutting precision and surgical tactile control, risk of adjacent tissue damage, mineralized tissue heating, integrity of the osteotomized surfaces, and post-operative healing. The evaluations demonstrated precisely delineated incisions and the need for limited pressure on the handpiece to achieve the desired cutting action, which improves surgical control and reduces the possibility of trauma to soft tissue.

10. Conclusion:

The performance and safety data presented in this premarket notification support a finding of substantial equivalence between the Piezosurgery bone cutting device and the predicate device specified in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 8 - 2005

Piezosurgery Srl
C/O Ms. Maria E. Donawa
President
Donawa Consulating Srl
Piazza Albania, 10
00153 Rome, Italy

Re: K043408
Trade/Device Name: Piezosurgery®
Regulation Number: 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZI
Dated: April 28, 2005
Received: May 2, 2005

Dear Ms. Donawa:

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.

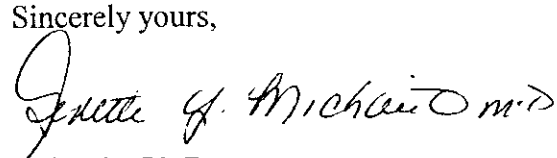
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number: K043408

Device Name: Piezosurgery®

Indications for Use: The Piezosurgery 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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