K122322

mectron medical technology

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DEC 0 6 2012

510(k) Summary in accordance with 21 CFR 807.92

Device Name:	Piezosurgery Touch
Type of 510(k) submission:	Traditional
Date of Submission:	July 30, 2012
Manufacturer:	Mectron Spa Via Loreto, 15, 16042 Carasco - (GE) Italy
FDA Registration Number:	3003933619
510(k) Owner:	Mectron Spa Via Loreto, 15, 16042 Carasco - (GE) Italy
510(k) Contact:	Roger Gray VP, Quality and Regulatory Donawa Lifescience Consulting Piazza Albania, 10, 00153 Rome, Italy Tel: +39 06 578 2665 Fax: +39 06 574 3786
Trade name:	Piezosurgery Touch
Common Name/Regulation Description:	Bone cutting instrument and accessories Ultrasonic scaler
Device Classification Name	Drill, Bone, Powered Ultrasonic scaler
Classification Regulation:	21 CFR 872.4120
FDA Panel:	Dental
Product Codes:	DZI ELC
Class:	Class II

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 6, 2012

Mectron S.PA.
C/O Mr. Roger Gray
Vice President, Quality and Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania, 10
Rome, Italy 00153

Re: K122322
Trade/Device Name: Piezosurgery Touch
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZI, ELC
Dated: November 30, 2012
Received: December 3, 2012

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. 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,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Indications for Use

510(k) Number (if known): K122322

Device Name: Piezosurgery Touch

Indications for Use: Piezosurgery Touch is a piezoelectric ultrasonic device, consisting of handpieces and associated tip inserts, intended for:

- **Bone cutting, osteotomy, osteoplasty and drilling** in a variety of oral surgical procedures, including implantology, periodontal surgery, surgical orthodontic, and surgical endodontic procedures;
- **Scaling applications**, including:
  - **Scaling:** All general procedures for removal of supragingival and interdental calculus & plaque deposits;
  - **Periodontology:** Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning;
  - **Endodontics:** All treatments for root canal reaming, irrigation, revision, filling, gutta-percha condensation and retrograde preparation;
  - **Restorative and Prosthetics:** Cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations and inlay/onlay condensation.

Prescription Use (Part 21 CFR 801 Subpart D)	X	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 DDS, MA 2012.12.06 12:17:02 -05'00'

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

510(k) Number:_____