Mectron S.p.a
% Karen Warden
Representative/Consultant
BackRoads Consulting, Inc
PO Box 566
Chesterland, Ohio 44026-0566

April 13, 2018

Re: K171326
Trade/Device Name: Piezosurgery White
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: DZI, ELC
Dated: March 12, 2018
Received: March 13, 2018

Dear Karen Warden:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171326

Device Name
Piezosurgery White

Indications for Use *(Describe)*

The Piezosurgery White 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for K171326

Date:	12 April 2018
Sponsor:	MECTRON S.p.A. Via Loreto 15 16042 Carasco - (GE) - ITALY Phone: +39 0185 35 361 Fax: +39 0185 351 374
Sponsor Contact:	Franco Zunino
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Trade Name:	Piezosurgery White
Common Name:	Powered bone drill with tip inserts and ultrasonic scaler
Regulatory Class:	Class II
Classification Name, Regulation, Product Codes:	Bone cutting instrument and accessories, 872.4120, DZI and Ultrasonic scaler, 872.4850, ELC
Submission Purpose:	To add the W1 - W6 inserts to the currently cleared Piezosurgery inserts offering.
Device Description:	The Piezosurgery White uses ultrasonic energy to generate mechanical micro-vibration of the available insert tips designed with different morphologies/shapes to perform the dental procedures defined in its intended use. The Piezosurgery White consists of a table-top unit (console) containing the irrigation delivery system, the internal electric power supply, the ultrasonic generator, and the control keyboard.
Indications for Use:	The Piezosurgery White 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.
Materials:	The Piezosurgery insert components are manufactured from stainless steels (ASTM F899).
Primary Predicate:	Piezosurgery White (MECTRON S.p.A – K151248)

Performance Data:	A features comparison and risk analysis of the modified devices was performed. The results demonstrate that the modifications do not alter the operating principle or mechanism of action of the inserts. The tuning frequency and vibration amplitude of each insert was evaluated via performance bench testing. The results demonstrated that the W1-W6 met the stipulated acceptance criteria and so are substantially equivalent to the predicate inserts.
Technological Characteristics:	The new Piezosurgery insert tips possess the same technological characteristics as the predicate device. These include: • intended use (as described above) • basic design (bone cutting accessories), and • material (medical grade stainless steel), The fundamental scientific technology of the additional Piezosurgery insert tips is the same as previously cleared device.
Conclusion:	The Piezosurgery White possesses the same intended use and technological characteristics as the predicate devices. Therefore Piezosurgery White is substantially equivalent for its intended use.