Mectron SPA
% Roger Gray
VP, Quality and Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania 10
Rome, 00153 It

January 11, 2018

Re: K171958
Trade/Device Name: Piezosurgery Touch, Piezosurgery White
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: DZI, ELC
Dated: December 7, 2017
Received: December 13, 2017

Dear Roger 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.

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

For
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)*
K171958

Device Name
Piezosurgery Touch and Piezosurgery White

Indications for Use *(Describe)*

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.

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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510(k) Summary in accordance with 21 CFR 807.92

1. ADMINISTRATIVE INFORMATION

510(k) submission number	K171958
Submission date:	28 November 2017
510(k) Owner and Submitter:	MECTRON S.p.a Via Loreto 15 16042 Carasco - (GE) - ITALY Phone: +39 0185 35 361 Fax: +39 0185 351 374
510(k) Submission Correspondent:	Roger Gray VP, Quality and Regulatory Donawa Lifescience Consulting Piazza Albania, 10 00153 Rome, Italy Phone: +39 06 578 2665 Fax: +39 06 574 3786 email: rgray@donawa.com
Manufacturer:	MECTRON S.p.a Via Loreto 15 16042 Carasco - (GE) – ITALY Establishment Registration Number: 3003933619

2. DEVICE

Trade name of the device:	Piezosurgery Touch and Piezosurgery White
Common Name/Regulation Description:	Bone cutting instrument and accessories
Classification Regulation:	21 CFR 872.4120
FDA Panel:	Dental
Product Code:	DZI, ELC
Classification:	Class II

3. IDENTIFICATION OF PREDICATE DEVICES

The substantial equivalence of the subject device is based on the following legally marketed primary predicate devices:

Trade name	Manufacturer	Product Codes	510(k) Number	Decision Date
Piezosurgery White	Mectron S.p.a	DZI, ELC	K151248	4 September 2015

In addition, two reference devices are cited in this submission, these being:

Trade name	Manufacturer	Product Codes	510(k) Number	Decision Date
Piezosurgery Touch	Mectron S.p.a	DZI, ELC	K122322	6 December 2012
Piezosurgery Device	Mectron S.p.a	DZI	K043408	8 June 2005

4. DEVICE DESCRIPTION

The Piezosurgery Touch and Piezosurgery White use ultrasonic energy to generate mechanical micro-vibrations of the available tip inserts to perform the dental procedures defined in its intended use.

They consist of a table-top unit (console) containing the irrigation delivery system, the internal electric power supply, the ultrasonic generator, and the control keyboard. They also includes the piezoelectric ultrasonic handpiece and foot-pedal, both connected directly to the console by means cords, and a variety of insert tips designed with different morphologies/shapes to be used for different dental procedures, according to device's intended use.

The table-top units use piezoelectric ultrasonic technology to generate mechanical micro-vibrations of the insert tip attached to the handpiece. A piezoelectric transducer, located inside the handpiece, and driven by the ultrasonic generator electronics, induces vibrations at ultrasonic frequencies in the insert tip.

The ultrasonic generator electronics searches and locates the resonant frequency of the transducer/insert tip combination, which varies according to the geometry/morphology of the insert tip in use. The functional ultrasonic frequency of the device is between approximately 24 and 36 kHz.

Each of the insert tips is available separately.

The purpose of this 510(k) is to add additional insert tip designs to the PIEZOSURGERY TOUCH and PIEZOSURGERY WHITE to extend the number of insert tips already cleared for sale in the US under K122322 and K151248.

5. 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.

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.

These indications for use statements are identical to those for the original unmodified (predicate) devices, as cleared under K122322 and K151248.

6. NEW INSERT TIPS:

The new insert tips are similar in design to tips already cleared with the PIEZOSURGERY TOUCH and PIEZSURGERY WHITE. The following are the model references of the insert tips being introduced by this submission:

SLC:	Osteoplasty insert
SLO-H:	Micrometric osteotomy insert
SLS:	Sinus membrane separator insert tip
SLE1:	Sinus membrane elevator insert tip
SLE2:	Sinus membrane elevator insert tip
PL1:	Osteotomy/osteoplasty insert
PL2:	Osteotomy/osteoplasty insert
PL3:	Osteotomy/osteoplasty insert

7. SUBSTANTIAL EQUIVALENCE

The new insert tips are substantially equivalent to insert tips already FDA-cleared for use with the Predicate Devices or the Reference Device, as follows:

Subject Insert Tip	Predicate Insert Tip	Predicate/Reference Device 510(k) #
SLC	OP3	K043408
SLO-H	OT1	K043408
SLS	EL1	K043408
SLE-1	EL2	K043408
SLE-2	EL3	K043408
PL1	OT5	K043408
PL2	OT9	K043408
PL3	OT11	K151248

Finite Element Analysis (FEA) was utilized in the design of the new insert tips to ensure that the resonant ultrasonic frequency of the inserts was within the functional ultrasonic frequency range of the Piezosurgery Touch and Piezosurgery White.

The new insert tips share the same intended uses as the identified predicate insert tips, have very similar operative part shapes, and functional testing has demonstrated compliance with specifications, thus no new issues of safety and effectiveness are raised.

8. NON-CLINICAL TESTING

The following non-clinical performance tests were completed.

Comparative performance bench testing:
This test compares the performances of the subject inserts (SLC, SLO-H, SLS, SLE1 and SLE2) to their predicate inserts (OP3, OT1, EL1, EL2 and EL3) in terms of tuning frequency and vibration amplitude in order to establish their substantial equivalence, concluding that:

- The tuning frequency of the new inserts and of their predicate inserts is between 24 and 36 kHz, which is the range of the device functional ultrasonic frequency.
- The vibration amplitude of the new inserts and of their predicate inserts have comparable values.

Reprocessing:
Separate cleaning and sterilization test have been carried out on a typical worst case reprocessed insert tip in order to successfully validate the reprocessing instructions provided with the reusable insert tips.

Biocompatibility:
A cytotoxicity growth inhibition test in L929 mouse fibroblasts, in accordance with ISO 10993-5:2009, was also carried out to demonstrate that a typical worst case reprocessed insert tip had *"no cytotoxic effects in all extracts in the growth inhibition test with L929 mouse fibroblasts"*.

9. CONCLUSION

Based on the information contained within this submission, the additional insert tips that are the subject of this submission, are substantially equivalent to the predicate device insert tips ~~with~~ of the Piezosurgery Touch and Piezosurgery White devices. It is concluded that the Piezosurgery Touch and Piezosurgery White devices that have been modified by the introduction of these new insert tips are substantially equivalent to the identified predicate devices cleared under K122322 and K151248, which are already in interstate commerce within the USA.