DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 4, 2015

MECTRON S.p.A.
c/o Mr. Roger Gray
Donawa Lifescience Consulting Srl
Piazza Albania, 10
00153 Rome
ITALY

Re: K151248
Trade/Device Name: Piezosurgery White
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone cutting instrument and accessories
Regulatory Class: II
Product Code: DZI, ELC
Dated: June 4, 2015
Received: June 8, 2015

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 contact 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. 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,

for Erin I. Keith, M.S.
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)*

K151248

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary in accordance with 21 CFR 807.92

1. ADMINISTRATIVE INFORMATION

Type of 510(k) submission:	Traditional
Submission date:	27 August 2015
510(k) Submitter:	MECTRON S.p.a Via Loreto 15 16042 Carasco - (GE) - ITALY Phone: +39 0185 35 361 Fax: +39 0185 351 374
510(k) Contact Person:	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 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 THE PREDICATE DEVICE

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

Trade name	Manufacturer	Product Codes	510(k) Number	Decision Date
Piezosurgery Touch	**Mectron S.p.a**	**DZI, ELC**	**K122322**	**12/06/2012**

4. DEVICE DESCRIPTION

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

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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. The device 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.

Inside the console are located the ultrasonic generator, the electrical power supply module and the microprocessor electronic board that controls and supervises the functional parameters of the device.

The console is connected to mains power by an electrical cord, and includes connectors for the handpiece and for the footswitch. One external peristaltic pump, intended for delivery of saline solution to the point of use, is attached to the console.

The console is equipped with a keyboard that allows the surgeon to set/control the functions of the device. The keyboard also provides monitoring information, by means icons, in case of malfunction of the device. The ultrasonic power and water flow are simultaneously activated by pressing the footswitch.

The ultrasonic generator of the Piezosurgery White is microprocessor-based and uses electronics to generate and control the appropriate drive signal (power and frequency) for the ultrasonic transducer, which is housed inside the handpiece.

The touch panel of the console allows setting of the following treatment/operative parameters:

- Six different types of treatment (IMPLANT, CORTICAL, CANCELLOUS, SPECIAL, PERIO, ENDO);
- Seven different levels of irrigation (from 0 to 6);
- The "pump/flush" function.

The Piezosurgery White uses piezoelectric ultrasonic technology to generate mechanical micro-vibrations of the tip insert 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 combination, which varies according to the geometry/morphology of the tip insert in use. The functional ultrasonic frequency of the device is between approximately 24 and 36 kHz. The Piezosurgery White handpiece transducer and family of inserts are designed to resonate in this range of frequencies.

The Piezosurgery White complies with the electrical safety and electromagnetic compatibility requirements established by the standards IEC 60601-1 and IEC 60601-1-2.

5. INTENDED USE/INDICATIONS FOR USE

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.

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6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Piezoelectric ultrasonic technology is used both by the subject and the predicate device to generate mechanical micro-vibrations of the insert connected to the handpiece. The subject device and predicate device share many characteristics, including identical piezoelectric transducers and ultrasonic generators, as shown in the following comparison table.

Item	**Subject Device** **Piezosurgery White**	**Predicate Device** **Piezosurgery Touch**	**Equivalence**
Manufacturer	MECTRON SPA Via Loreto 15 16042 Carasco - Italy	MECTRON SPA Via Loreto 15 16042 Carasco - Italy	N/A
510(k) Number	Subject of this submission	K122322	N/A
FDA Panel	Dental	Dental	Same
Regulation Number and name	872.4120 - Bone cutting instrument and accessories	872.4120 - Bone cutting instrument and accessories 872.4850 - Ultrasonic Scaler	Same
Product Code	DZI, ELC	DZI, ELC	Same
Regulatory Class	Class II	Class II	Same
Technological Characteristics (mechanism of action)	Piezoelectric ultrasonic technology which generates mechanical micro-vibrations of the insert tips. The piezoelectric transducer uses piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the insert tip.	Piezoelectric ultrasonic technology which generates mechanical micro-vibrations of the insert tips. The piezoelectric transducer uses piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the insert tip.	Same
Device type	Table top device	Table top device	Same
Indications for Use / Intended Use	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.	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.	Same

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Item	Subject Device Piezosurgery White	Predicate Device Piezosurgery Touch	Equivalence
Main device components	• Control unit with integrated irrigation peristaltic pump, electric power supply and ultrasonic generator. • Piezoelectric ultrasonic handpiece and cord. • Torque wrench to tighten the inserts on the hand piece. • Footswitch with cord. • Bracket/s for irrigation solution bag. • Power supply cord. • Range of insert tips to be used according to the dental applications defined by the intended use. • Other accessories/attachments.	• Control unit with integrated irrigation peristaltic pump, electric power supply and ultrasonic generator. • Piezoelectric ultrasonic handpiece and cord. • Torque wrench to tighten the inserts on the hand piece. • Footswitch with cord. • Bracket/s for irrigation solution bag. • Power supply cord. • Range of insert tips to be used according to the dental applications defined by the intended use. • Other accessories and attachments.	Same
Transducer technological characteristics	Piezoelectric: The transducer uses four hard piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the insert tip.	Piezoelectric: The transducer uses four hard piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the insert tip.	Same
Automatic resonance frequency tuning	Electronics with automatic frequency tuning.	Electronics with automatic frequency tuning.	Same
Modulated amplitude of the ultrasonic signal mode	Yes	Yes	Same
Output performance specification	Operational Vibration frequency: 24 kHz to ~ 36 kHz. Max. Output: 25 Watt	Operational Vibration frequency: 24 kHz to ~ 36 kHz. Max. Output: 25 Watt	Same
Supply Voltage	100 - 240 VAC	100 - 240 VAC	Same
Output Modes	Six output modes identified as Endo, Perio, Special, Cancellous, Cortical and Implant on the touch panel.	Six output modes identified as Endo, Perio, Special, Cancellous, Cortical and Implant on the touch panel.	Same
Activation	Footswitch connected to the control console by means of a cord.	Footswitch connected to the control console by means of a cord.	Same
Irrigation system	Irrigation bag connected to a peristaltic pump. Adjustable irrigation flow rate.	Irrigation bag connected to a peristaltic pump. Adjustable irrigation flow rate.	Same
Adjustable irrigation flow rate.	Seven irrigation flow rates, from 0 to 75 ml/min	Seven irrigation flow rates, from 0 to 75 ml/min	Same
Electrical safety	Complies with IEC 60601-1	Complies with IEC 60601-1	Same
Electromagnetic Compatibility	Complies with IEC 60601-1-2	Complies with EN 60601-1-2 which is equivalent to IEC 60601-1-2	Same
Does the device contain software?	Yes	Yes	Same
Software Validation	In accordance with FDA Guidance: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"	In accordance with FDA Guidance: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"	Same
Parts need to be sterilized	Yes	Yes	Same
Recommended sterilization method	Autoclaving (Steam Sterilization)	Autoclaving (Steam Sterilization)	Same
Single use parts	Diamond coated inserts	Diamond coated inserts	Same

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Item	Subject Device Piezosurgery White	Predicate Device Piezosurgery Touch	Equivalence
Tip Inserts	Material: Stainless steel The insert tips are secured to the handpiece by a thread, using a torque wrench.	Material: Stainless steel The insert tips are secured to the handpiece by a thread, using a torque wrench.	Same
Console Dimensions	Width: 298,5 mm Height: 84 mm Depth: 245 mm	Width: 300 mm Height: 95 mm Depth: 250 mm	Very similar

7. SUBSTANTIAL EQUIVALENCE DISCUSSION

The Piezosurgery White and the predicate device, Piezosurgery Touch, share identical indications for use / intended use.

Both devices combine the functions of a bone cutting instrument and of an ultrasonic dental scaler.

Piezosurgery White uses the same fundamental technology as the predicate device, utilizing the same piezoelectric ultrasonic technology to generate mechanical micro-vibration of the insert tips fitted onto the handpiece.

The ultrasonic generator of the Piezosurgery White, which generates and controls the appropriate drive signal (power and frequency) to the transducer, is identical in design, manufacture and function to the ultrasonic generator used in the predicate device, Piezosurgery Touch, including the availability of a low frequency burst mode.

Apart from the minor cosmetic differences existing between the external designs of the subject and predicate device cases, both the subject device and the predicate device consist essentially of a table-top unit with incorporated touch keyboard, peristaltic pump, footswitch, ultrasonic handpiece/s, hoses/connectors, a variety of tips for bone cutting, and a torque wrench for attaching the tips to the handpiece.

Compared to predicate device, Piezosurgery White presents the same operational characteristics and user interface, including identical, operating parameters, which can be selected/adjusted by the operator through the keyboard, specifically: Six output modes, seven pre-set flow rates of the irrigation fluid, and a ‘Pump/Flush’ function that allows the operator to prime the entire irrigation circuit

The touch keyboard of the predicate device Piezosurgery Touch has the additional function “Light” that allows the operator to manage the LED illumination of the handpiece, whereas on the subject device, when a handpiece incorporating an LED light is used, it is switched on by pressing the foot-pedal.

Except for ten new inserts, introduced with this submission, whose minimal differences compared to predicate inserts and/or to equivalent manual instruments do not raise new questions of safety or performance, all the inserts intended for use with the Piezosurgery White have been previously cleared by FDA for use with the predicate device.

Inserts PR1 and PR2, introduced in this submission, have shapes and intended use similar to existing manual periosteal elevators, having a frontal semi-circular profile with a radius of 2 mm and 5 mm respectively. The shape and dimensions of these inserts are suitable for generating ultrasonic longitudinal vibrational behaviour that mimics use of manual periosteal elevators to allow periosteum detachment by following the anatomical profile.

Inserts PR1 and PR2 have very similar shapes and designs to already-cleared inserts OP3 and EL3, having circular flat geometry of the operative part. Insert EL3 also has a very similar use to inserts PR1 and PR2, being intended for detaching/separating the sinus membrane.

Finite Element Analysis (FEA) was utilized in the design of inserts PR1 and PR2 to ensure that the resonant ultrasonic frequency of the inserts was within the functional ultrasonic frequency range of the

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Piezosurgery White. Functional bench tests conducted on inserts PR1 and PR2 when attached to the Piezosurgery White handpiece verify that the operative resonant frequency of the inserts is within the functional ultrasonic frequency range of the Piezosurgery White.

Inserts PR1 and PR2 share the same intended use as manual periosteal elevators, 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. SUMMARY OF NON-CLINICAL TESTING

Non-clinical testing was performed on the Piezosurgery White and associated inserts to support the claims of substantial equivalence, including:

- Testing to confirm compliance with safety requirements of IEC 60601-1.
- Testing to confirm compliance with EMC requirements of IEC 60601-1-2.
- Testing to confirm compliance with the safety requirements of IEC 80601-2-60.
- Software documentation, verification and validation in accordance with FDA guidance: 'Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices', 11 May 2005.
- Sterilization validation in accordance with ISO 17665-1 and ISO 14937.
- Bench tests to demonstrate substantial equivalence to the predicate device, including:
  - Current to the handpiece.
  - Working frequency range.
  - Leakage current.
  - Ultrasonic transduction power.
  - Ultrasonic frequency range and amplitude of vibration for inserts PR1 and PR2.

9. CONCLUSION

The subject device, Piezosurgery White, and the predicate device, Piezosurgery Touch, share the same intended use, principle of operation, technological characteristics to generate ultrasonic mechanical vibrations of the associated tip inserts, and range of available insert tips, with no differences that raise new questions of safety and effectiveness.

The majority of tip inserts included in this submission for use with the subject device are identical to those cleared within the 510(k) submission of the predicate device. The new tip inserts introduced within this submission are manufactured from the same materials, with similar morphologies, and sterilized by the same methods as those cleared previously by FDA with the predicate device.

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