DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 5, 2015

Mectron Spa
c/o Mr. Roger Gray
Donawa Lifescience Consulting Srl
Piazza Albania, 10
Rome, 00153
ITALY

Re: K151023
Trade/Device Name: Compact Piezo LED
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic scaler
Regulatory Class: II
Product Code: ELC
Dated: May 4, 2015
Received: May 7, 2015

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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)*
K151023

Device Name
COMPACT PIEZO LED

Indications for Use *(Describe)*
The Compact Piezo Led is an ultrasonic scaler device intended for use, with the appropriate associated insert tips, in the following dental applications:

• Scaling: Procedures for removal of supragingival/subgingival and interdental calculus/plaque deposits;
• Periodontology: Periodontal therapy and debridement for periodontal diseases, including periodontal pocket irrigation and cleaning;
• Endodontics: Treatments for root canal reaming irrigation, revision, filling, gutta-percha condensation and retrograde preparation;
• Restorative and Prosthetics: Restorative procedures including cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations, inlay/onlay condensation and implants/restorations cleaning.

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 for Mectron Compact Piezo Led

1. ADMINISTRATIVE INFORMATION

Type of 510(K) submission:	Traditional 510(k) Submission
Submission date:	4 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:	Compact Piezo Led
Common Name / Regulation Description:	Ultrasonic scaler
Regulation Number:	21 CFR 872.4850
Classification:	Class II
FDA Panel:	Dental
Product Code:	ELC

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3. PREDICATE DEVICES

The substantial equivalence of the Compact Piezo Led is based on the legally marketed predicate devices identified in Table 1:

Table 1: Predicate Devices

Trade name	Predicate reference	Manufacturer	Product Code	510(k) Number	Decision Date
Compact Piezo P2k	**PD1 (primary)**	**Mectron S.p.a**	**ELC**	**K102218**	**01/24/2011**
Multipiezo	**PD2 (reference)**	**Mectron S.p.a**	**ELC**	**K140965**	**08/20/2014**

- The piezoelectric ultrasonic handpiece and the ultrasonic generator that are supplied with the subject device are identical/very similar to those described in the 510(k) submissions for these predicate devices.
- The tip inserts intended for use with the subject device were previously cleared by FDA within the 510(k)s of these predicate devices.

4. DEVICE DESCRIPTION

The Compact Piezo Led is a multipurpose piezoelectric ultrasonic scaler sub-assembly device intended to be supplied to manufacturers of dental unit devices and incorporated within such devices, to be used for ultrasonic treatment in scaling, periodontics, endodontics and prosthetics dental applications.

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

The Compact Piezo Led consists of an ultrasonic generator, a handpiece/cord incorporating a led light, a range of insert tips, a torque wrench, different wiring connection kits, and other minor accessories.

The range of tip inserts, handpiece and torque wrench are autoclavable.

The subject device is intended to be assembled inside a dental unit and connected to the dental unit's electrical supply by the wiring connection kit provided.

The handpiece/cord is connected directly to the device's ultrasonic generator, from which it receives the functional drive signals, including those for irrigation supply, from the dental unit. The ultrasonic power and water flow are simultaneously activated by pressing the footswitch of the dental unit. The power output and water flow are adjusted through the dental unit's controls.

The ultrasonic generator of the Compact Piezo Led 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 ultrasonic generator electronics search and locate the resonant frequency of the transducer/insert tip 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 Compact Piezo Led handpiece transducer and family of inserts are designed to resonate within this frequency range.

The Compact Piezo Led device complies with the electrical safety and electromagnetic compatibility requirements established by the standards IEC 60601-1 and IEC 60601-1-2.

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5. INTENDED USE/INDICATIONS FOR USE

The Compact Piezo Led is an ultrasonic scaler device intended for use, with the appropriate associated insert tips, in the following dental applications:

- Scaling: Procedures for removal of supragingival/subgingival and interdental calculus/plaque deposits;
- Periodontology: Periodontal therapy and debridement for periodontal diseases, including periodontal pocket irrigation and cleaning;
- Endodontics: Treatments for root canal reaming irrigation, revision, filling, gutta-percha condensation and retrograde preparation;
- Restorative and Prosthetics: Restorative procedures including cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations, inlay/onlay condensation and implants/restorations cleaning.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

Piezoelectric ultrasonic technology is used both by the subject and the predicate devices to generate mechanical micro-vibrations of the insert connected to the handpiece. The subject device and predicate devices share the same piezoelectric transducers, very similar ultrasonic generators, and same insert tips.
Similarities and differences between the subject device and the predicate devices are summarized in Table 2.

Table 2: Predicate Device Comparison Table

Description	Subject Device Compact Piezo Led	Predicate Device 1 (PD1) Compact Piezo P2K Primary Predicate	Predicate Device 2 (PD2) Multipiezo Reference Predicate	Explanation of differences SE#
FDA panel	Dental	Dental	Dental	Identical to PD1 & PD2
Regulation # and name	872.4850 – Ultrasonic Scaler	872.4850 – Ultrasonic Scaler	872.4850 - Ultrasonic Scaler	Identical to PD1 & PD2
Product Code	ELC	ELC	ELC	Identical to PD1 & PD2
Classification	Class II	Class II	Class II	Identical to PD1 & PD2
Technological Characteristics (mechanism of action)	Piezoelectric ultrasonic technology that generates mechanical micro-vibration 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 that generates mechanical micro-vibration 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 that generates mechanical micro-vibration of the insert tips. The piezoelectric transducer uses piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the insert tip.	Identical to PD1 & PD2
Device type	Sub-assembly device intended to be incorporated into a dental unit and/or table top device	Sub-assembly device intended to be incorporated into a dental unit and/or table top device	Table top device	Identical to PD1. **SE#1**

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Description	Subject Device Compact Piezo Led	Predicate Device 1 (PD1) Compact Piezo P2K Primary Predicate	Predicate Device 2 (PD2) Multipiezo Reference Predicate	Explanation of differences SE#
Indications for use/Intended use	The Compact Piezo Led is an ultrasonic scaler intended for use, with the appropriate associated insert tips, in the following dental applications: • Scaling: Procedures for removal of supragingival/ subgingival and interdental calculus/plaque deposits; • Periodontology: Periodontal therapy and debridement for periodontal diseases, including periodontal pocket irrigation and cleaning; • Endodontics: Treatments for root canal reaming irrigation, revision, filling, gutta-percha condensation and retrograde preparation; • Restorative and Prosthetics: Restorative procedures including cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations, inlay/onlay condensation and implants/restorations cleaning.	The Compact Piezo P2K device is an ultrasonic scaler intended for use with the appropriate associated insert tips, in the following dental applications: • Scaling: All general scaling applications including removal of supra/sub gingival/ interdental calculus/plaque deposits; • Periodontology: Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning; • Endodontics: All endodontics procedures including treatments for root canal reaming, irrigation, revision, filling, gutta-percha condensation and retrograde preparation; • Restorative and Prosthetics: All general restorative procedures including cavity preparation, removal of prostheses, amalgam, condensation and finishing of crown preparation and inlay/onlay condensation.	The Multipiezo Pro and Multipiezo are piezoelectric ultrasonic dental scalers intended for use, with the appropriate associated tip inserts, in the following dental applications: • Scaling: All general procedures for removal of supragingival/subgingival 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: All general restorative procedures including cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations, inlay/onlay condensation, implants/restorations cleaning.	Very similar to PD1 & PD2
Transducer Technological characteristics	Piezoelectric: The transducer uses four piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the insert tip	Piezoelectric: The transducer uses four piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the insert tip	Piezoelectric: The transducer uses four piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the insert tip	Identical to PD1 & PD2
Automatic resonant frequency tuning	Electronics with automatic frequency tuning	Electronics with automatic frequency tuning	Electronics with automatic frequency tuning	Identical to PD1 & PD2
Led system incorporated inside the handpiece to provide illumination of the operative site.	Yes	No	Yes	Identical to PD2. **SE#2**
Irrigation supply source	Through irrigation line of the dental unit where the Compact Piezo Led is mounted.	Through irrigation line of the dental unit where the Compact Piezo P2K is mounted.	Two irrigation sources: A refillable irrigation bottle mounted on the console connected to peristaltic pump, or alternatively external water supply by means of an optional accessory.	Identical to PD1. SE#3

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Description	Subject Device Compact Piezo Led	Predicate Device 1 (PD1) Compact Piezo P2K Primary Predicate	Predicate Device 2 (PD2) Multipiezo Reference Predicate	Explanation of differences SE#
Irrigation flow rate adjustment	Through the flow regulator of the dental unit	Through the flow regulator of the dental unit	Flow rate adjustable through the touch panel of the console	Identical to PD1. **SE#4**
Feedback system control	The power is automatically adjusted as a function of the resistance encountered by the insert tip during the treatment.	The power is automatically adjusted as a function of the resistance encountered by the insert tip during the treatment.	The power is automatically adjusted as a function of the resistance encountered by the insert tip during the treatment.	Identical to PD1 & PD2
upply Voltage	Powered through the dental unit: 24 VAC ± 10% or 32 VDC ± 10%.	Powered through the dental unit: 24 VAC ± 10% or 32 VDC ± 10%.	100 - 240 VAC – 50/60 Hz	Identical to PD1. **SE#5**
Output performance specifications	Output: 15 Watt Frequency range: 24 kHz to ~36 kHz	Output: 15 Watt Frequency range: 24 kHz to ~36 kHz	Output: 15 Watt Frequency range: 24 kHz to ~36 kHz	Identical to PD1 & PD2
Power Activation	Activation through the dental unit	Activation through the dental unit	Foot-pedal connected to the control console by means of a cord	Identical to PD1. **SE#6**
lectrical safety	Complies with IEC 60601-1	Complies with IEC 60601-1	Complies with IEC 60601-1	Identical to PD1 & PD2
Electromagnetic Compatibility	Complies IEC 60601-1-2	Complies IEC 60601-1-2	Complies IEC 60601-1-2	Identical to PD1 & PD2
Does the device contain software?	Yes	Yes	Yes	Identical to PD1 & PD2
Differences in Software	Software controls device integrated with third party dental unit, including Led illumination at tip	Software controls device integrated with third party dental unit.	Software control stand-alone unit, including Led illumination of tip	Different from PD1 & PD2 **SE#7**
Software Documentation	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'	In accordance with FDA Guidance: 'Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices'	Identical to PD1 & PD2
Parts need to be sterilized before use?	Yes	Yes	Yes	Identical to PD1 & PD2
Recommended sterilization method	Autoclaving (Steam Sterilization)	Autoclaving (Steam Sterilization)	Autoclaving (Steam Sterilization)	Identical to PD1 & PD2
Parts supplied sterile?	No	No	No	Identical to PD1 & PD2
ingle use parts	Diamond coated inserts	Diamond coated inserts	Diamond coated inserts	Identical to PD1 & PD2
ip Inserts	Raw Material: Stainless steel. The insert tips are secured to the handpiece by a thread, using a torque wrench.	Raw Material: Stainless steel. The insert tips are secured to the handpiece by a thread, using a torque wrench.	Raw Material: Stainless steel. The insert tips are secured to the handpiece by a thread, using a torque wrench.	Identical to PD1 & PD2
imensions	46 x 71 x 34 mm (ultrasonic generator module)	46 x 71 x 34 mm (ultrasonic generator module)	440 x 230 x 145 mm (table top device console	Identical to PD1. **SE#8**

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7. SUBSTANTIAL EQUIVALENCE DISCUSSION

With specific reference to the SE#s identified in Table 1 related to differences between one or both of the predicate devices and the subject device, Table 2 provides an explanation of the differences.

Table 2: Discussion of differences between predicates and subject device.

SE#	SE Discussion
SE #1	PD 1 is identical to the subject device. PD 2 is a stand-alone table top ultrasonic scaler device, comprising a console with a panel control to which are connected to the handpiece, the footswitch and the power supply cord. The subject device is intended to be integrated inside a dental unit manufactured by a third party, whereas PD 2 is a stand-alone table top device. This difference between the subject device and PD 2 does not raise any new or different questions .
SE #2	PD 2 is identical to the subject device. Compared with PD 1, the hand piece of the subject device incorporates Led illumination in order to improve visibility of the operative site. Testing was carried out by third party test laboratory according to IEC 62471:2006 – 'Photobiological safety of lamps and lamp systems' and found to be in compliance. The Led system incorporated in the handpiece of the subject device does not raise any new or different questions .
SE #3	PD 1 is identical to the subject device. The subject device is intended to be assembled inside a dental unit, receiving functional drive signals, including those for irrigation supply, from the dental unit. PD 2 is a stand-alone table top unit which has the irrigation system integrated in its console. Therefore with the subject device, the operator adjusts irrigation flow by means of the dental unit's control panel, while with PD 2, irrigation flow is adjusted by means of the integrated control panel, from either an attached fluid bottle or from an external fluid supply. This difference does not raise any new or different questions.
SE #4	See above point SE 3
SE #5	PD 1 is identical to the subject device. The subject device is intended to be assembled inside a dental unit and powered from a power source internal to the dental unit. The proposed device receives the functional drive signals, including electrical power, from the dental unit. PD 2 is a stand-alone table top device connected to mains power. This difference does not raise any new or different questions.
SE #6	PD 1 is identical to the subject device. The subject device is intended to be assembled inside a dental unit and to receive its functional signals from the dental unit. PD 2 is a stand-alone table top device connected to mains power, with its functional signals being generated internally. This difference does not raise any new or different questions .
SE #7	Compared to PD1 the software of the subject device has been modified to allow the generator module to drive the led illumination on the handpiece, together with a modification to allow use of a 'soft' operative mode. Compared to PD2 the software of the subject device is different because the PD2 is a table top device which includes control of elements that the subject device does not have, ie. touch screen, peristaltic pump, etc. The software for PD2 includes control of the led illumination and use of 'soft' mode, however. Since the software of the subject device has been validated in accordance with FDA Guidelines, the differences existing between the subject device and predicate device software do not raise any new or different questions .
SE #8	PD 1 is identical to the subject device. The dimensional differences between the subject device and PD2 are as a result of the need for the additional electronic components to be incorporated into PD2, because all functional signals are generated internally, rather than some being received from an external source. This difference does not raise any new or different questions .

8. SUMMARY OF NON-CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

The Compact Piezo Led complies with the electrical safety and electromagnetic compatibility established by standards IEC 60601-1, IEC 60601-1-2 and IEC 80601-2-60.

Non-clinical testing of the subject device includes:

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- Testing to confirm compliance of the Compact Piezo Led with the safety requirements of standard IEC 60601-1.
- Testing to confirm compliance with EMC requirements of standard IEC 60601-1-2.
- Testing to confirm compliance with the safety requirements of standard IEC 80601-2-60.
- Software Verification and Validation.
- Functional testing to confirm: current delivered to the handpiece, working frequency range, leakage currents, ultrasonic transducer power.
- Direct comparison of functional test results with the predicate devices

9. CONCLUSION

The subject device, Compact Piezo Led, and the predicate devices, Compact Piezo P2K and Multipiezo, share the same intended uses, principles 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.

The tip inserts included in this submission are identical to those cleared within the 510(k) submissions of the predicate devices.

Based on the information contained within this submission, it is concluded that the Mectron Compact Piezo Led is substantially equivalent to the identified predicate devices already in interstate commerce within the USA.