DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 20, 2014

Mectron Spa
C/O Mr. Roger Gray
VP, Quality and Regulatory
Donawa Lifescience Consulting
Piazzz Albania, 10,
00153 Rome, Italy

Re: K140965
Trade/Device Name: Multipiezo Pro, Multipiezo
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: May 20, 2014
Received: May 23, 2014

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 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,

Mary S. Runner -S

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

Indications for Use Statement

510(k) Number (if known): K140965

Device Name: Mectron Multipiezo Pro and Multipiezo Dental Scalers

Indications for Use: 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.

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)

mectron medical technology

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K140965

510(k) Summary in accordance with 21 CFR 807.92

Device Name:	Multipiezo Pro Multipiezo
Type of 510(k) submission:	Traditional
Date of Submission:	April 9, 2014
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
Common Name/Regulation Description:	Scaler, ultrasonic
Classification Regulation:	21 CFR 872.4850
FDA Panel:	Dental
Product Code:	ELC
Class:	Class II

Two devices, Multipiezo Pro and Multipiezo, have been bundled in this single 510(k) submission. The devices share the following identical functional/technical characteristics:

- Same Intended Use/Indications for Use
- Same Technological Characteristics (mechanism of action)
- Same accessories (insert tips, etc.)
- Same operative modes/signal information
- Same parts to be sterilized and sterilization methods
- Same performance

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Intended Use/Indications for use
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.

Device Description and Technological Characteristics:
The Multipiezo Pro and Multipiezo devices are dental piezoelectric ultrasonic devices that use ultrasonic energy to generate mechanical micro-vibration of the inserts to perform the dental procedures defined in their intended use.

The Multipiezo Pro consists of a base control unit (console) with two integrated peristaltic pumps which deliver irrigation liquid, contained in two independent detachable 500 ml bottles, to two sterilizable ultrasonic handpieces with connecting cords. The selection of the irrigation fluid occurs automatically when the operator removes the handpiece from the support associated with the tank containing the liquid that the dentist wants to use for the treatment. Only one handpiece can be used at a time.

The Multipiezo device consists of a base control unit with a single integrated peristaltic pump which delivers the irrigation liquid contained in one detachable tank to one single ultrasonic handpiece with connecting cord.

The consoles of both devices are connected to mains power by an electrical cord, and include connectors for the hand piece/s and for the footswitch. The consoles incorporate peristaltic pump/s which provide/s the irrigation fluid contained in the tank/s to the operation site.

The handpiece contains a piezoelectric ultrasonic transducer which is connected to the ultrasonic generator (inside the console) by a cable at one end and to which tip inserts are attached at the other end.

The ultrasonic generator, identical in both devices, is microprocessor-based and uses electronics to generate and control the appropriate drive signal (power and frequency) for the transducer in the handpiece. A touch screen on the console of both devices allows the setting of treatment parameters, as follows:

- Four type of functions (Endo, Perio/Scaler, Restorative, Soft Mode) that can be adjusted through 6 power levels
- Seven different levels of irrigation (from 0 to 6)
- Insert tip illumination (on, off or auto)
- Flush function.

Non clinical testing
The Multipiezo Pro and Multipiezo devices comply with the electrical safety and electromagnetic compatibility requirements established by the standards IEC 60601-1 and IEC 60601-1-2.

Bench testing of the subject devices includes:

- Testing to confirm compliance with the safety requirements of standard IEC 60601-1
- Testing to confirm compliance with EMC requirements of standard IEC 60601-1-2

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Substantial Equivalence
The substantial equivalence of the subject devices is based on the following predicate devices:

- EMS Piezon Master 600, manufactured by Electro Medical System SA, 510(k) reference K022328, cleared on 13 August 2002.
- Compact Piezo P2K, manufactured by Mectron Spa, 510(k) reference K102218, cleared on 24 January 2011.

The technological characteristics and operating parameters of the Multipiezo Pro and Multipiezo are identical or very similar to those of the predicate devices. With respect to the functional aspects, the Multipiezo Pro and Multipiezo use the same fundamental technology as the two predicate devices.

Both the subject devices and the predicate devices use same piezoelectric technology to generate mechanical micro-vibration to the inserts to perform the dental ultrasound treatments according to their intended use.

Both the subject devices and the two predicate devices have the ultrasonic transducers housed in the respective handpieces. The transducers of the Multipiezo Pro and Multipiezo and of the predicate devices are formed by piezoceramic disks which convert the input electrical power to mechanical vibration of the insert.

Any differences between the subject device and one or other of the predicate devices is not significant with regard to device safety or effectiveness

Conclusion
The Multipiezo pro and Multipiezo and the predicate devices share the same general intended use and technology.

The differences existing between the subject devices and the predicate devices relating to technical specifications, performance and intended use are minor and do not affect safety and effectiveness.

The data presented in this submission demonstrate the similarities in the intended use/indications of use and technology existing between the Multipiezo Pro and Multipiezo devices and the referenced predicate devices, and thus supports a finding of substantial equivalence between the subject device and the predicate devices which are already in commercial distribution in the United States.