DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 27, 2015

E.M.S. Electro Medical Systems
C/O Ms. Tina Wu
Aptiv Solutions
62 Forest Street, Suite 300
Marlborough, MA, 01752

Re: K140990/S002
Trade/Device Name: PIEZON® 707 BIK and PIEZON® BIK LED
Regulation Number: 21 CFR 872.4850
Regulation Name: Scaler, Ultrasonic
Regulatory Class: Class II
Product Code: ELC
Dated: January 26, 2015
Received: January 28, 2015

Dear Ms. Wu:

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,

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)*
K140990

Device Name
PIEZON® 707 BIK and PIEZON® BIK LED

Indications for Use *(Describe)*
The PIEZON® 707 BIK and PIEZON® BIK LED is intended for use for the following indications:
Scaling
• Removal of supragingival calculus
• Removal of stains
Endo
• Preparation, cleaning and irrigation of root canals
• Condensing gutta-percha
• Removal of crowns, bridges and restorations
Restorative
• Preparation of cavities
• Cementation of restorations
• Condensing of amalgams
Periodontics
• Scaling and root planing
• Periodontal therapy

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 the
E.M.S. ELECTRO MEDICAL SYSTEMS SA
PIEZON® 707 BIK and PIEZON® BIK LED

1. SUBMITTER/510(K) HOLDER

E.M.S. ELECTRO MEDICAL SYSTEMS SA
Ch. de la Vuarpillière 31
CH - 1260 Nyon
Switzerland

Contact Person: Suzanne Fassio-Hardy
Telephone: (41) 22 99 44 700
Date Prepared: February 26, 2015

2. DEVICE NAME

Proprietary Name: PIEZON® 707 BIK and PIEZON® BIK LED
Common/Usual Name: Ultrasonic scaler
Classification Name: Scaler, Ultrasonic (21 CFR 872.4850, Product Code ELC)

3. PREDICATE DEVICES

The PIEZON® 707 BIK and PIEZON® BIK LED is substantially equivalent to the Satelec SP Newtron Module, cleared for marketing in K033764.

The Piezon Handpiece and Piezon Handpiece LED that are supplied with the proposed device were described in the 510(k) Premarket Notification for the Piezon 150 and Piezon 250 (K132443 and K132445) and the Piezon Master 700 (K093000), respectively.

The instruments used with the Piezon Handpiece and Piezon Handpiece LED were previously cleared by FDA:

- E.M.S. ELECTRO MEDICAL SYSTEMS S.A., miniMaster Ultrasonic Scaler (K050710)
- E.M.S. ELECTRO MEDICAL SYSTEMS S.A., EMS Kermit (K992504)
- E.M.S. ELECTRO MEDICAL SYSTEMS S.A., miniPiezon (K953026)
- E.M.S. ELECTRO MEDICAL SYSTEMS S.A., Piezon Master 400 (K896749)
- E.M.S. ELECTRO MEDICAL SYSTEMS S.A., Piezon Master 600 (K022328)
- E.M.S. ELECTRO MEDICAL SYSTEMS S.A., Piezon Master 700 (K093000)
- E.M.S. ELECTRO MEDICAL SYSTEMS S.A., Piezon 150 (K132443)
- E.M.S. ELECTRO MEDICAL SYSTEMS S.A., Piezon 250 (K132445)

4. DEVICE DESCRIPTION

The PIEZON® 707 BIK and PIEZON® BIK LED is an ultrasonic scaling unit consisting of an ultrasonic generator supplied with a Piezon Handpiece and scaling instruments. The PIEZON® 707 BIK and PIEZON® BIK LED are supplied with the Piezon Handpiece EN-061 and Piezon Handpiece LED EN-060, respectively. The PIEZON® 707 BIK and PIEZON® BIK LED ultrasonic generator is designed for installation into a dental chair.

The ultrasonic generator produces piezo-electric vibrations (ultrasonics) for water or dry work instruments. The appropriate instrument for a particular application is screwed onto the handpiece supplied with the scaling unit prior to beginning the procedure. The power control is handled via the potentiometer or the chair main control. The water control is handled via the handpiece or the chair main control. The treatment is carried out by placing the instrument tip onto the tooth surface according to the Operating Instruction for the instrument selected.

5. INDICATION FOR USE/INTENDED USE

The PIEZON® 707 BIK and PIEZON® BIK LED is intended for use for the following indications:

<u>Scaling</u>
- Removal of supragingival calculus
- Removal of stains

<u>Endo</u>
- Preparation, cleaning and irrigation of root canals
- Condensing gutta-percha
- Removal of crowns, bridges and restorations

<u>Restorative</u>
- Preparation of cavities
- Cementation of restorations
- Condensing of amalgams

<u>Periodontics</u>
- Scaling and root planing
- Periodontal therapy

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE.

The proposed PIEZON® 707 BIK and PIEZON® BIK LED is substantially equivalent to the previously cleared SP Newtron Module, K033764. The electric power supply of the proposed device (24 VAC ± 10%, 33 VDC ± 10%) is within the same range as the predicate (24 VAC ± 10%, 35 VDC ± 10%) and the 2 VDC difference is not significant given that in both devices, there range of ± 10%. Although the maximum power consumption of the proposed device is 14 VA and the predicate is 30 VA, this is indicative that the proposed PIEZON® 707 BIK and PIEZON® BIK LED consumes less power to function. The 1 Watt difference in the maximum power output between the proposed (8 Watt) and predicate (9 Watt) still produces similar instrument vibrations. In terms of frequency, the proposed device operates at 24 to 32 kHz and the predicate at 28 to 36 kHz – this difference does not affect the performance of the compatible EMS instruments. Finally, the water pressure of the proposed device (1-2 bars) is within range of the predicate (1-3 bars). Taken together, the differences in the design (e.g., dimensions of the module) and the aforementioned specifications of the proposed device do not affect its safety or performance. Furthermore, testing demonstrated that the PIEZON® 707 BIK and PIEZON® BIK LED fulfil the prospectively defined performance specifications.

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

Non-clinical performance testing demonstrates that all design inputs for the PIEZON® 707 BIK and PIEZON® BIK LED were satisfied by the design outputs. Testing of the device, when integrated with a dental chair and handpiece was performed. Results of the integration testing showed that the device met electrical safety (IEC 60601-1) and electromagnetic compatibility (IEC 60601-1-2) requirements. Additional integration testing included basic and essential performance as well as validation of the software in its actual use. Results from the functional and performance testing showed that the device met the predetermined acceptance criteria. The similarities in intended use, operational characteristics, and functional technological characteristics between the proposed PIEZON® 707 BIK and PIEZON® BIK LED and the parent SP Newtron Module lead to a conclusion of substantial equivalence between the proposed and predicate device.

The results of this testing confirm that the PIEZON® 707 BIK and PIEZON® BIK LED is as safe and effective as the predicate device for the intended use described in Section 5.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was conducted to support this submission.

9. SUMMARY OF OTHER INFORMATION

No other information is available.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

The similarities in intended use, operational characteristics, and functional technological characteristics between the proposed PIEZON® 707 BIK and PIEZON® BIK LED and the predicate SP Newtron Module lead to a conclusion of substantial equivalence between the proposed and predicate device. A side-by-side comparison of the predicate device and the proposed device is provided in the table at the end of this section.

Table 5-1. Side-by-Side Comparison of the PIEZON® 707 BIK and PIEZON® BIK LED with Predicate Device

Features	PIEZON® 707 BIK and PIEZON® BIK LED	SP Newtron Module
Regulatory status	**Proposed**	**K033764**
Indications for use	Scaling • Removal of supragingival calculus • Removal of stains Endo • Preparation, cleaning and irrigation of root canals • Condensing gutta-percha • Removal of crowns, bridges and restorations Restorative • Preparation of cavities • Cementation of restorations • Condensing of amalgams Periodontics • Scaling and root planing • Periodontal therapy	Scaling • Interdental junction treatment • Tooth neck and subgingival treatment • Treatment of large deposits • Treatment of coating and tobacco stains • Interproximal treatment • Prosthesis conservative/restorative: - Inlay/onlay condensation - Amalgam plugging - Loosening prostheses (bridge, crown, post, pivot...) Endodontia: • Canal preparation • Canal cleaning • Canal filling • Gutta percha condensation • Treatment resumption • Retro surgery • Micro retro surgery • Surface smoothing after burring Periodontia: • Root planing • Initial therapy • Treatment of periodontal pockets • Treatment of furcations • Maintenance therapy • Implant maintenance
Electric power supply	• 24 VAC ± 10% • 33 VDC ± 10%	• 24 VAC ±10%, 50/60Hz, 35VA • 35 VDC ±10%, 30Watt

Features	PIEZON® 707 BIK and PIEZON® BIK LED	SP Newtron Module
Maximum power consumption	14 VA	30 VA
Maximum power output	8 Watt	9 Watt
Frequency	24 to 32 kHz	28 to 36 kHz
Mode	Continuous	Continuous
Water delivery system	Connection to external water supply. 1-2 bars.	Connection to external water supply. 1-3 bars.
Cruise control	Yes	Yes
Control Light	Option with LED driver	Option with LED driver
Module	34 x 60 x 50 mm	60 x 49 x 33mm
Connection to second scaler unit	Not allowed	Not allowed