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# PIEZON 150
# Special 510(k): Device Modification
# 510(k) Summary
# (per 21 CFR 807.92(c))
# K132443

## 1. SUBMITTER/510(K) HOLDER

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

Contact Person: Suzanne Fassio-Hardy
Telephone: 022 994 47 00

Date Prepared: October 24, 2013

## 2. DEVICE NAME

| | |
|---|---|
| Proprietary Name: | PIEZON 150 |
| Common/Usual Name: | Ultrasonic Scaler |
| Classification Name: | Ultrasonic Scaler (21 CFR 872.4850, Product Code ELC) |

## 3. PREDICATE DEVICES

The proposed PIEZON 150 is a modification of the E.M.S. ELECTRO MEDICAL SYSTEMS S.A., miniPiezon (K953026).

The Piezon Handpiece LED that is compatible with the proposed device was described in the 510(k) premarket notification for the Piezon Master 700 (K093000).

The instruments used with the PIEZON 150 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)

## 4. DEVICE DESCRIPTION

The proposed PIEZON 150 ultrasonic scaler is a modification of the previously cleared miniPiezon (K953026). The working instrument for the scaling function is the handpiece, which is connected to the control unit via a handpiece cord and mounted in a holder on the side of the control unit.

The PIEZON 150 connects to an external water supply and delivers water via the connected handpiece. The power of ultrasonic vibrations is adjusted via a power knob on the top of the control unit. The flow rate of the irrigating liquid is adjusted via a rotating knob located on the side of the control unit.

The PIEZON 150 is supplied with two handpieces – the Piezon Handpiece LED (light-emitting diode) or the Piezon Handpiece. The Piezon Handpiece LED is identical to the Piezon Handpiece LED described in K093000 for the Piezon Master 700 ultrasonic scaler (K093000) and contains 6 LEDs in the body of the handpiece and a light guide that is positioned under the nozzle. The Piezon Handpiece is identical to the Piezon Handpiece LED, except that the Piezon Handpiece does not have LEDs or the light guide. All instruments compatible with the PIEZON 150 have been previously cleared (see 510(k) numbers referenced in Section 3).

The modifications made to the miniPiezon to produce the PIEZON 150 include:

- Shape and contours of the control unit redesigned to accommodate the finger-tip power control, improve aesthetics, facilitate cleaning, and enhance ergonomics
- Use of a potentiometer for power regulation via the power control knob to improve ultrasonic power control.
- One operating mode with a Standard power range (0-100% power) for scaling procedures and a Perio range (0-37.5% power) for periodontal procedures
- Supported handpieces (Piezon Handpiece (FT-215#) and Piezon Handpiece LED (FT-223#)
- Ultrasonic generator upgraded to EJ-110. In EJ-110, the Light command, Motor/Solenoid valve command and Pedal command have been added.

## 5. INTENDED USE

The PIEZON 150 is a device for delivering ultrasonic movement and water to a stainless steel tip which is used by a dentist or dental hygienist. The indications for use are:

- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planing

- Removal of supra and subgingival calculus and stains from teeth

## 6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

The proposed PIEZON 150 is similar in design and materials to the parent miniPiezon. Both the proposed and parent devices are ultrasonic scalers consisting of a control unit housing an ultrasonic generator that produces piezo-electric vibrations to perform the scaling function. The working instrument for both the proposed and predicate devices is the handpiece, which is connected to a control unit via a handpiece cord. A scaling instrument specific to a particular scaling procedure is attached to the end of the handpiece. Both the proposed and predicate ultrasonic scalers connect to an external water supply and deliver water via the connected handpiece.

Differences between the proposed PIEZON 150 and the predicate miniPiezon and the Piezon Master 700 are limited to the compatible handpieces and the control unit modifications to improve ergonomics and ultrasonic power control described in Section 4. The similarities and differences between the proposed and parent devices are illustrated in the table at the end of this section.

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

Non-clinical performance testing demonstrates that all design inputs for the PIEZON 150 were satisfied by the design outputs, that the device meets electrical safety and electromagnetic compatibility requirements, and functional and performance requirements. The similarities in intended use, operational characteristics, and functional technological characteristics between the proposed PIEZON 150 and the parent miniPiezon and predicate Piezon Master 700 lead to a conclusion of substantial equivalence between the proposed and predicate devices.

## 8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was conducted for 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 150 and the parent miniPiezon and predicate Piezon Master 700 lead to a conclusion of substantial equivalence between the proposed and predicate devices. A side-by-side comparison of the predicate devices and the proposed device is provided in the table at the end of this section.

**Comparison Table for Determination of Substantial Equivalence**
**PIEZON 150, EMS miniPiezon, and Piezon Master 700**

| Item for Comparison | PIEZON 150 (FT-215#) Piezon Handpiece Proposed | PIEZON 150 (FT-223#) Piezon Handpiece LED Proposed | Piezon Master 700 K093000 | EMS miniPiezon K953026 |
|---|---|---|---|---|
| Indications for Use | The PIEZON 150 is a device for delivering ultrasonic movement and water to a stainless steel tip which is used by a dentist or dental hygienist. The indications for use are:<br>• Periodontal pocket lavage with simultaneous ultrasonic tip movement<br>• Scaling and root planning<br>• Removal of supra and subgingival calculus and stains from teeth<br>• Intended for use in dental and periodontal applications performed by an ultrasonic scaler. | | The Piezon Master 700 is an ultrasonic scaler intended for use in the following dental and periodontal applications:<br>• Removing supra and subgingival calculus deposits and stains from teeth<br>• Periodontal pocket lavage with simultaneous ultrasonic tip movement<br>• Scaling and root planing<br>• Releasing crowns, bridges, inlays, and posts as well as condensing gutta percha<br>• Plugging for amalgam condensation<br>• Amalgam burnishing<br>• Preparing, cleaning and irrigating root canals<br>• Cavity preparation<br>• Cementing inlays and onlays<br>• Retrograde preparation of root canals | The miniPiezon is a device for delivering ultrasonic movement and water to a stainless steel tip which is used by a dentist or dental hygienist. The indications for use are:<br>• Periodontal pocket lavage with simultaneous ultrasonic tip movement<br>• Scaling and root planning<br>• Removal of supra and subgingival calculus and stains from teeth<br>• Intended for use in dental and periodontal applications performed by an ultrasonic scaler. |
| Treatment Site | Subgingival and supragingival | Subgingival and supragingival | Subgingival and supragingival | Subgingival and supragingival |
| Function | Ultrasonic scaling | Ultrasonic scaling | Ultrasonic scaling | Ultrasonic scaling |
| Mechanism of action | Ultrasonic energy | Ultrasonic energy | Ultrasonic energy | Ultrasonic energy |
| Components | • Control Unit<br>• Foot pedal<br>• Piezon Handpiece*<br>• Instruments+<br>• Water hose with screwed connector on device | • Control Unit<br>• Foot pedal<br>• Piezon Handpiece* LED<br>• Instruments+<br>• Water hose with screwed connector on device | • Control Unit<br>• Foot pedal<br>• Piezon Handpiece LED<br>• Instruments*<br>• Irrigation liquid bottle | • Control Unit<br>• Foot pedal<br>• Universal Piezon Handpiece<br>• Instruments+<br>• Water hose with quick connector on device |
| Power supply | • External 30V transformer<br>• 50-60 Hz | • External 30V transformer<br>• 50-60 Hz | • Internal transformer 24V<br>• 50–60 Hz | • External 24V transformer<br>• 50-60 Hz |
| Ultrasonic power adjustment | Power control knob using a potentiometer | Power control knob using a potentiometer | Touch sensitive zones on front panel of housing | • Adjustment key "-" or "+" on the panel of housing |

| Item for Comparison | PIEZON 150 (FT-215#) Piezon Handpiece Proposed | PIEZON 150 (FT-223#) Piezon Handpiece LED Proposed | Piezon Master 700 K093000 | EMS miniPiezon K953026 |
|---|---|---|---|---|
| Water adjustment | • Connection to external water supply<br>• Rotating knob for control of water flow rate | • Connection to external water supply<br>• Rotating knob for control of water flow rate | • Rotary ring on handpiece hose | • Connection to external water supply<br>• Rotating knob for control of water flow rate |
| Output performance specifications | • Maximum output: 8Watts<br>• Frequency range: 24-32 kHz | • Maximum output: 8Watts<br>• Frequency range: 24-32 kHz | • 0 – 12W (max. power delivered is 8W)<br>• 24 – 32 kHz | • Maximum output: 8 W<br>• Frequency range: 25-32kHz |
| Power range | • Standard: 0-100%<br>• Perio0-37.5% | • Standard: 0-100%<br>• Perio0-37.5% | • Standard:0-100%<br>• Endo: 0 – 50% | 0-100% |

*Previously cleared in K093000
+All instruments previously cleared (see Section 3)

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

November 22, 2013

E.M.S. Electro Medical Systems S.A.
C/O Aptiv Solutions
Ms. Cynthia J.M. Nolte
Director, Medical Device Regulatory Services
62 Forest Street, Suite 300
Marlborough, MA 01752

Re: K132443
Trade/Device Name: PIEZON 150
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class:
Product Code: ELC
Dated: October 24, 2013
Received: October 25, 2013

Dear Ms. Nolte:

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,

Mary S. Brimer -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K132443

# Indications for Use

510(k) Number (if known):

Device Name: PIEZON 150

Indications for Use:

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- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planing
- Removal of supra and subgingival calculus and stains from teeth

Prescription Use _X_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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