November 1, 2019

E.M.S Electro Medical Systems S.A
℅ Christina Henza
Regulatory
Ultra LifeScience Solutions Inc.
872 S. Milwaukee Ave #286
Libertyville, Illinois 60048

Re: K191079
Trade/Device Name: Piezon Built-in Kit, Piezon Built-in Kit LED
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic scaler
Regulatory Class: Class II
Product Code: ELC
Dated: May 20, 2019
Received: May 20, 2019

Dear Christina Henza:

This letter corrects our substantially equivalent letter of August 16, 2019.

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha -S

Digitally signed by Michael E. Adjodha -S
Date: 2019.11.01 07:05:39 -04'00'

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191079

Device Name
PIEZON BUILT-IN KIT

Indications for Use *(Describe)*
Scaling:
- Removal of supragingival and subgingival calculus
- Removal of stains

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 PIEZON BUILT-IN KIT – K191079

I. Date: August 8, 2019

II. SUBMITTTER/ 510(K) HOLDER

E.M.S. Electro Medical Systems S.A.
Ch. de la Vuarpillière 31
CH - 1260 Nyon
Switzerland

Primary Contact:

Suzanne FASSIO-HARDY,
Regulatory Affairs Manager – Dental
Direct: +41 22 99 44 771
Email: sfassiohardy@ems-ch.com

Submission Contact:

Christina Henza
Regulatory Affairs Consultant
872 S. Milwaukee Ave #286
Libertyville, IL 60048
+1 262 220 3463
chenza@ultralifescience.com

III. DEVICE NAME

Proprietary Name: PIEZON BUILT-IN KIT
Common/Usual Name: Ultrasonic scaler
Classification Name: Ultrasonic scaler (872.4850)
Device Class: II
Product Code: ELC

IV. PREDICATE DEVICES

E.M.S. Electro Medical Systems S.A., Piezon 150 (K132443 cleared on 11/22/2013).
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

V. DEVICE DESCRIPTION

The proposed devices, PIEZON BUILT-IN KIT and the PIEZON BUILT-IN KIT LED, represent a change in presentation from the stand alone PIEZON 150 (predicate) to a device which

is built in to the dental chair (OSSTEM K3 (K152830)). The proposed device and the predicate device are both manufactured using the same internal componentry, the only difference is that instead of housing the device for stand alone use, the componentry is installed into a dental chair.

The difference between PIEZON® BUILT-IN KIT LED and PIEZON® BUILT-IN KIT is that the handpiece of the first features integrated light (LED) while the second does not. All other aspects are identical. Each system consists of the wireless module and handpiece cord and is provided with a wire harness for installation as well as the appropriate accessories. Additionally, spare parts are available.

As with other ultrasonic scalers, the ultrasonic generator component of the PIEZON BUILT-IN KIT and PIEZON BUILT-IN KIT LED (Piezon® Module EJ-110, installed in a dental chair) generates piezo-electric vibrations (ultrasonics) for water or dry work instruments. The PIEZON BUILT-IN KIT and PIEZON BUILT-IN KIT LED are supplied with the Piezon Handpiece EN-061/OS and Piezon Handpiece LED EN-060/OS, respectively. Instruments mounted in the Piezon Handpiece or Piezon Handpiece LED vibrates with a controlled oscillatory movement when activated.

Instruments A is supplied as part of all kits. Instruments P and PS are additionally included in the kits with OS1 suffix. The appropriate instrument for the particular application is screwed onto the handpiece prior to beginning the procedure. The treatment is carried out by placing the instrument tip onto the tooth surface according to the Operating Instruction for the instrument selected.

VI. INDICATIONS FOR USE

Scaling:
- Removal of supragingival and subgingival calculus
- Removal of stains

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS OF PROPOSED COMPARED TO THE PREDICATE DEVICE

The proposed device and the predicate device have equivalent technological characteristics. The proposed device and the predicate device are both manufactured using the same internal componentry. The devices meet the same performance specifications and the change in presentation from a stand alone device to a built in device has been validated.

The safety and effectiveness questions regarding the change in presentation from a stand alone device to a built in device are whether the device maintains electrical safety / compatibility characteristics and whether the use is adequately described within the instructions. These questions apply to both the proposed device and the predicate; the proposed device does not raise different questions of safety and efficacy.

Therefore, the proposed devices, PIEZON BUILT-IN KIT & PIEZON BUILT-IN KITLED, meets substantial equivalence requirements with regards to the legally marketed predicate PIEZON 150 (K132443 cleared on 11/22/2013).

Substantial Equivalence Table				
Item for Comparison		**Proposed Device (PIEZON BUILT-IN KIT & PIEZON BUILT-IN KIT LED)**	**Predicate Device (PIEZON 150)**	**Variation**
Regulatory Information	Name	PIEZON BUILT-IN KIT & PIEZON BUILT-IN KIT LED	Piezon 150	N/A
	510(k)#	K191079	K132443	N/A
	Predicates	K132443	K953026 & K093000	N/A
	Product Code	ELC	ELC	Same.
	Class	2	2	Same.
	Combination Product	No	No	Same.
	Regulation Number	872.4850	872.4850	Same.
	Regulation Generic Name	Ultrasonic scaler	Ultrasonic scaler	Same.
Intended use	Regulation Intended Use	"for use during dental cleaning and periodontal (gum) therapy to remove calculus deposits from teeth by application of an ultrasonic vibrating scaler tip to the teeth"	"for use during dental cleaning and periodontal (gum) therapy to remove calculus deposits from teeth by application of an ultrasonic vibrating scaler tip to the teeth"	Same.
	Indications	Scaling: - Removal of supragingival and subgingival c alculus - Removal of stains	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 planning - Removal of supra and subgingival calculus and stains from teeth.	Equivalent.
	Contraindications	It is recommended not to treat patients with a cardiac pacemaker or a defibrillator with this product. The functionality of these devices may be affected by the high frequencies of the ultrasonic oscillations.	Ultrasonic oscillations may prevent cardiac pacemakers and defibrillators from functioning properly. Therefore, we recommend that patients with a cardiac pacemaker or a defibrillator should not be treated with this product	Same.

Substantial Equivalence Table				
		Proposed Device (PIEZON BUILT-IN KIT & PIEZON BUILT-IN KIT LED)	**Predicate Device (PIEZON 150)**	**Explanation of Variation**
Technological Characteristics	Anatomical sites	Teeth and soft tissues in the mouth.	Teeth and soft tissues in the mouth	Same.
	Specific Treatment site	Supragingival	Supra and Subgingival	Equivalent.
	Contact duration	Limited ≤ 24 hours	Limited ≤ 24 hours	Same.
	Biocompatibility	Biocompatible	Biocompatible	Same.
	Patient Contact Material	Stainless Steel PPSU EPDM Stainless steel: AISI 316L Titanium COC	Stainless Steel PPSU EPDM Stainless steel: AISI 316L Titanium COC	Same.
	Sterility	Provided non-sterile	Provided non-sterile	Same.
	Shelf life	unrestricted	unrestricted	Same.
	General purpose	dental cleaning and periodontal (gum) therapy	dental cleaning and periodontal (gum) therapy	Same.
	Treatment	Ultrasonic Scaling	Ultrasonic Scaling	Same.
	Mechanism of treatment	application of an ultrasonic vibrating scaler tip to the teeth	application of an ultrasonic vibrating scaler tip to the teeth	Same.
	Service pressure to the turbine connection: Water	1 to 2.2 bar (1000-2200 hPa) with a service flow of 50-80 ml/min.)	1 to 2.2 bar (1000-2200 hPa) with a service flow of 50-80 ml/min.)	Same.
	Service pressure to the turbine connection: Air	Static pressure 2.7 to 3.5 bar (2700-3500 hPa	Static pressure 2.7 to 3.5 bar (2700-3500 hPa	Same.
	Electric power supply	• 24 VAC ± 10% • 33 VDC ± 10%	• 100-240 VAC • 50-60Hz • 30VDC	Equivalent.
	Ultrasonic generator	EJ-110F/A (configuration of EJ-110A/D)	EJ-110A/D	Same
	Maximum power output	8 Watt	8 Watt	Same
	Frequency	24 to 32 kHz	24 to 32 kHz	Same
	Mode	Continuous	Continuous	Same
	Water delivery system	Connection to external water supply	Connection to external water supply	Same
	Cruise control	Yes	Yes	Same
	Software	ES-002 rev a, version 1.5	ES-002 rev a, version 1.5	Same
	Control Light	Option with LED driver	Option with LED driver	Same
	Handpiece	EN-060/OS with LED EN-061/OS without LED	EN-060 (FT-223#) with LED EN-061 (FT-215#) without LED	Same
	Operating conditions	+10 °C to +40 °C 30% to 75% relative humidity Altitude max. 3000	+10 °C to +40 °C 30% to 75% relative humidity Altitude max. 3000	Same
	Transport and storage conditions	-10 °C to +40 °C 10% to 95% relative humidity 500 hPa to 1060 hPa air pressure	-10 °C to +40 °C 10% to 95% relative humidity 500 hPa to 1060 hPa air pressure	Same
	Housing	Installed into dental chair	Stand alone device	Equivalent.

VIII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

A Risk Assessment was performed to review associated risks for this configurable Piezon kit assembly which consists of parts for ultrasonic treatment that are incorporated into a dental unit (chair). This initial risk assessment includes clinical and device specific risks for the PIEZON BUILT-IN KIT alone. An additional risk analysis was performed to address the risk of the product as a subsystem of a treatment unit (dental chair) to include any additional or changed risks that arise from the inclusion of the kit as a component of a dental chair. The combination of these two Risk Analyses were prepared to determine the necessary safety measures in design and manufacturing. The risks related to all applicable hazards which were identified for the PIEZON BIK have been reduced to the acceptable level by mitigation. Therefore, all residual risks post-mitigation have been deemed acceptable for this design.

There are no changes to any functional specifications or components included in this submission. The proposed device and the predicate device are both manufactured using the same internal componentry, and the same attached accessories; the only difference is that instead of housing the device for stand alone use, the componentry is installed into a dental chair.

Biocompatibility

Biocompatibility assessment was performed according to ISO 10993-1 and no testing was necessary since all patient contacting components are identical to the cleared predicate – Piezon 150 (K132443).

Electrical Safety and Electromagnetic Compatibility Testing:

Electrical Safety and Electromagnetic Compatibility are equivalent to the predicate device based on IEC 60601-1 & IEC 60601-1-2. All tests passed and conformance is confirmed.

Integration Testing:

To verify that the removal of the housing unit and incorporation into a dental chair does not impact the performance of the BIK, functional testing was completed on the integrated product to confirm product functionality. Integration testing includes both verification of device installation into the chair as per installation specifications and confirmation of product functionality.

All tests were successfully performed and all acceptance criteria were met, thus confirming that the PIEZON BUILT-IN KIT and the PIEZON BUILT-IN KIT LED satisfactorily meet requirements. No new questions of safety and effectiveness were identified during review of Risk Management documentation or during execution of testing.

IX. CONCLUSIONS

Based on the information and supporting documentation provided in the premarket notification, the PIEZON BUILT-IN KIT and the PIEZON BUILT-IN KIT LED are substantially

equivalent to the cited predicate device. Testing demonstrates that the PIEZON BUILT-IN KIT fulfills prospectively defined design and performance specifications.