E.M.S. Electro Medical Systems S.A.
c/o Christina Henza
Regulatory
Can-Do-Medical
31 CH. de la Vuarpillière
CH – 1260 Nyon
Switzerland

December 18, 2017

Re: K171174
Trade/Device Name: PERIO-FLOW nozzle
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EFB
Dated: November 17, 2017
Received: November 17, 2017

Dear Christina Henza:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting 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)*

K171174

Device Name
PERIO-FLOW nozzle

Indications for Use *(Describe)*

The PERIO-FLOW nozzle, used with EMS PERIO-FLOW dental handpieces, is intended for patients suffering from periodontal disease.

The PERIO-FLOW nozzle, used with EMS PERIO-FLOW dental handpieces, is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

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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.

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K171174

510 (K) SUMMARY FOR PERIO-FLOW nozzle

I. SUBMITTTER/ 510(K) HOLDER

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II. Date Prepared: December 14, 2017

III. DEVICE NAME

Proprietary Name: PERIO-FLOW nozzle
Common/Usual Name: Accessories
Classification Name: Dental Handpiece and Accessories (872.4200)
Device Class: I
Product Code: EFB

IV. PREDICATE DEVICES

Primary Predicate: E.M.S. Electro Medical Systems S.A., AIR-FLOW handy 3.0 PERIO (K132480 cleared on 02/24/2014

V. DEVICE DESCRIPTION

The PERIO-FLOW nozzle is a flexible, thermoplastic accessory to the PERIO-FLOW handpiece that is used with the EMS AIR-FLOW devices such as AIR-FLOW MASTER, AIR-FLOW MASTER PIEZON and AIR-FLOW handy PERIO and AIR-FLOW handy 3.0 Perio. The PERIO-FLOW nozzle includes printed markings and is molded from an alternate version of the cleared thermoplastic polyester elastomer. The marks are arranged to ensure that the user is aware of the location of the tip with respect to the pocket. There is a

mark at 3 mm and 5 mm so that the user can evaluate the location of the tip during a procedure. The 5mm mark is bolder to indicate the depth limit. The line and the square located above the 5 mm line serve to ensure that the user does not insert the nozzle deeper than 5mm in the pocket. The PERIO-FLOW nozzle is provided non-sterile. The nozzle is single use only and is intended for use under clean conditions.

The principle of operation of the proposed PERIO-FLOW nozzle is identical to predicate device nozzle (DT-113) which was cleared with the predicate system AIR-FLOW handy 3.0 PERIO (K132480 cleared on 02/24/2014).

EMS dental handpieces connect to a standard turbine connection on a dental operative unit and deliver a mixture of water, air, and the prophylaxis powder to a treatment site. The air /powder mixture exits the distal end of the PERIO-FLOW handpiece through the PERIO-FLOW nozzle where it meets with a water spray in the pocket.

VI. INDICATIONS FOR USE

The PERIO-FLOW nozzle, used with EMS PERIO-FLOW dental handpieces, is intended for patients suffering from periodontal disease.

The PERIO-FLOW nozzle, used with EMS PERIO-FLOW dental handpieces, is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

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

The proposed PERIO-FLOW nozzle is an additional accessory intended to be used with all currently available EMS PERIO-FLOW dental handpieces. The substantial equivalence claim is specific to the nozzle accessory within the predicate submission, all other system components are unaffected by this submission.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Nozzle Geometry (general shape and hole placement)
- Projection of water/air/powder mixture
- Use with PERIO (Glycine) powder

The following technological differences exist between the subject and predicate devices:

- The material is a different thermoplastic polyester elastomer
- The subject device includes printed markings

The questions regarding the material change and addition of markings are whether it is biocompatible and whether the use is adequately described within the instructions. These questions apply to both the new device and the predicate. Therefore, the proposed device, PERIO-FLOW nozzle, is substantially equivalent with regards to the nozzle portion of the legally marketed predicate AIR-FLOW handy 3.0 PERIO (K132480 cleared on 02/24/2014).

Substantial Equivalence Table				
Item for Comparison		**Proposed Device (PERIO-FLOW Nozzle DT-476)**	**Predicate Device (PERIO-FLOW Nozzle DT-113)**	**Explanation of Variation**
Regulatory Information	Name	PERIO-FLOW nozzle	EMS AIR-FLOW handy 3.0 PERIO	N/A
	510(k)#	K171174	K132480	N/A
	Predicates	K132480	K082791	N/A
	Product Code	EFB	EFB	Same.
	Class	1	1	Same.
	Combination Product	No	No	Same.
	Regulation Number	872.4200	872.4200	Same.
	Regulation Generic Name	Dental Handpiece and Accessories	Dental Handpiece and Accessories	Same.
Intended use	Regulation Intended Use	"to prepare dental cavities for restorations, such as fillings, and for cleaning teeth."	"to prepare dental cavities for restorations, such as fillings, and for cleaning teeth."	Same.
	Indications	The PERIO-FLOW nozzle, used with EMS PERIO-FLOW dental handpieces, is intended for patients suffering from periodontal disease. The PERIO-FLOW nozzle, used with EMS PERIO-FLOW dental handpieces, is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.	The AIR-FLOW handy 3.0 PERIO is intended for patients suffering from periodontal disease. The AIR-FLOW handy 3.0 PERIO is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.	Same.
Technological Characteristics	Treatment Site	Subgingival	Subgingival	Same.
	Anatomical sites	Teeth and soft tissues in the mouth.	Teeth and soft tissues in the mouth	Same.
	Specific Treatment site	Subgingival	Subgingival	Same.
	Contact duration	Limited ≤ 24 hours	Limited ≤ 24 hours	Same.
	Biocompatibility	Biocompatible	Biocompatible	Same.
	Material	Thermoplastic Polyester Elastomer Ink (printed markings)	Thermoplastic Polyester Elastomer	Equivalent.
	Sterility	Provided non-sterile	Provided non-sterile	Same.
	Shelf life	unrestricted	unrestricted	Same.
	General purpose	Cleaning and surface preparation	Cleaning and surface preparation	Same.
	Treatment	Air-polishing	Air-polishing	Same.
	Mechanism of treatment	Projection of water/air/powder mixture	Projection of water/air/powder mixture	Same.
	Compatible Prophylaxis Powders	PERIO (Glycine)	PERIO (Glycine)	Same.
	Mode	continuous operation	continuous operation	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.

Substantial Equivalence Table				
Item for Comparison		**Proposed Device (PERIO-FLOW Nozzle DT-476)**	**Predicate Device (PERIO-FLOW Nozzle DT-113)**	**Explanation of Variation**
	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.
	Nozzle Geometry	20.3mm in length, the width of the device at the taper is 2.96 mm thick where the taper begins near the shoulder and 2.03mm thick near the tip	20.3mm in length, the width of the device at the taper is 2.96 mm thick where the taper begins near the shoulder and 2.03mm thick near the tip	Same.

VIII. PERFORMANCE DATA

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

Biocompatibility testing:

The biocompatibility evaluation for the PERIO-FLOW nozzle was conducted in accordance with the FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (Attachment A)* published June 16, 2016. This device is categorized in *ISO 10993-1:2009* as "Surface device - breached or compromised surface" per section 5.2.1(c). The device will have limited contact of less than or equal to 24 hours. Testing completed on this device includes:

- Cytotoxicity
- Sensitization
- Irritation

Comparison Testing:

To verify that the nozzles will work with the specified dental handpieces, comparison testing was completed on the current material (predicate) and the new material (this submission) for the nozzle. Comparison testing consisted of measuring connection force, pressure resistance, and nozzle fixation.

To verify that the change of material does not impact the performance on the nozzle, functional testing was completed on the current material (predicate) and the new material (this submission) for the nozzle. Functional testing consisted of confirming the placement of powder exit holes on the nozzle, the direction of powder exits, and the durability of the markings.

All tests were successfully performed and all acceptance criteria were met.

IX. CONCLUSIONS

Based on the information and supporting documentation provided in the premarket notification, the PERIO-FLOW nozzle is substantially equivalent to the cited predicate device. Testing demonstrates that the PERIO-FLOW nozzle fulfills prospectively defined design and performance specifications.