October 20, 2019

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

Re: K190124
Trade/Device Name: EMS AIRFLOW Prophylaxis Master, EMS AIRFLOW One
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC, KOJ
Dated: September 19, 2019
Received: September 20, 2019

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. 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,

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)*
K190124

Device Name
EMS AIRFLOW Prophylaxis Master

Indications for Use *(Describe)*
The AIRFLOW Prophylaxis Master combines the functions of an ultrasonic scaler and air-polishing unit within a single chassis. The AIRFLOW Prophylaxis Master is intended for use in the following dental and periodontal applications:
• Removing supra and subgingival calculus deposits and stains from teeth
• Periodontal pocket lavage with simultaneous ultrasonic tip movement
• Scaling and root planing
• Releasing crowns, bridges, inlays, and posts as well as condensing gutta percha
• Plugging for amalgam condensation
• Amalgam burnishing
• Preparing, cleaning and irrigating root canals
• Cavity preparation
• Cementing inlays and onlays
• Retrograde preparation of root canals

The AIRFLOW Prophylaxis Master is intended for use in the cleaning and polishing of teeth by the projection of water, air, and dental powders onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth.
The AIRFLOW Prophylaxis Master can be used for the following cleaning procedures:
• plaque removal for placement of sealants
• surface preparation prior to bonding/cementation of inlays, onlays, crowns and veneers
• surface preparation prior to placing composite restorations
• effective plaque and stain removal for orthodontic patients
• cleaning prior to bonding ortho brackets
• cleaning implant fixture prior to loading
• stain removal for shade determination
• plaque removal prior to fluoride treatment
• plaque and stain removal prior to whitening procedure

The AIRFLOW Prophylaxis Master is also intended for use as an air-polisher in patients suffering from periodontal disease. The AIRFLOW Prophylaxis Master is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

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."

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)*
K190124

Device Name
EMS AIRFLOW One

Indications for Use *(Describe)*

The AIRFLOW One is intended for use in the cleaning and polishing of teeth by the projection of water, air, and dental powders onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth.

The AIRFLOW One can be used for the following cleaning procedures:

- plaque removal for placement of sealants
- surface preparation prior to bonding/cementation of inlays, onlays, crowns and veneers
- surface preparation prior to placing composite restorations
- effective plaque and stain removal for orthodontic patients
- cleaning prior to bonding ortho brackets
- cleaning implant fixture prior to loading
- stain removal for shade determination
- plaque removal prior to fluoride treatment
- plaque and stain removal prior to whitening procedure

The AIRFLOW One is also intended for use as an air-polisher in patients suffering from periodontal disease. The AIRFLOW One is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

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)

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SECTION 5: 510(k) Summary

Traditional 510(k) Premarket Notification

E.M.S. Electro Medical Systems S.A.
EMS AIRFLOW Prophylaxis Master and EMS AIRFLOW One

510(k) Summary

1. Submitter/510(k) Holder

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

Primary Contact Person: Gaëlle Pacaud
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Submission Contact: Christina Henza
chenza@ultralifescience.com

Date Prepared: January 14, 2019

2. Device Name

Proprietary Name: EMS AIRFLOW Prophylaxis Master
Common/Usual Name: Ultrasonic Scaler/Air Polishing Unit
Classification Name: Ultrasonic Scaler (21 CFR 872.4850)
Device Class: II
Product Code: ELC*

**The EMS AIRFLOW Prophylaxis Master combines the functions of an ultrasonic scaler and air-polishing unit. The predicate AIR-FLOW MASTER PIEZON, which was cleared with dual ultrasonic scaling and air-polishing functions, was classified by FDA as an ultrasonic scaler.*

Proprietary Name: EMS AIRFLOW One
Common/Usual Name: Air Polishing Unit
Classification Name: Airbrush (21 CFR 872.6080)
Device Class: II
Product Code: KOJ

3. Predicate Devices

The proposed EMS AIRFLOW Prophylaxis Master and AIRFLOW One are substantially equivalent to the legally marketed AIR-FLOW MASTER PIEZON (K110173, cleared on 04/07/2011). This predicate has not been subject to a design-related recall. No reference devices were used in this submission.

4. Device Description

The EMS AIRFLOW Prophylaxis Master is a dental device that combines the functions of an ultrasonic scaler and air-polishing unit within a single chassis. The proposed device consists of a control unit, hoses, handpiece cords for the two handpieces and a foot pedal which can be wired or wireless. There are two repositories on the control unit: one for the irrigation liquid container or the waterline cleaner container and the other one for one of both air-polishing powder chambers supplied with the device.

The AIRFLOW Prophylaxis Master is supplied with the Piezon Handpiece LED for performing ultrasonic scaling functions. The proposed device is compatible with EMS instruments legally marketed for ultrasonic scaling procedures.

The AIRFLOW Prophylaxis Master is also supplied with the AIR-FLOW Handpiece and optionally with the PERIO-FLOW Handpiece and the PERIO-FLOW Nozzles marked for performing air-polishing procedures. The proposed device is compatible with the AIR-FLOW CLASSIC new formula (sodium bicarbonate), AIR-FLOW SOFT (glycine), AIR-FLOW PERIO (glycine) and AIR-FLOW PLUS (Erythritol) prophylaxis powders.

The AIRFLOW Prophylaxis Master is supplied with accessories for attaching and removing instruments and nozzles from the handpieces.

The EMS AIRFLOW One is the same device as the EMS AIRFLOW Prophylaxis Master without the ultrasonic scaling function. Therefore, the description of the AIRFLOW Prophylaxis Master is also applicable to the AIRFLOW One, except the part related to the ultrasonic scaling function.

5. Indications for Use

The AIRFLOW Prophylaxis Master combines the functions of an ultrasonic scaler and air-polishing unit within a single chassis. The AIRFLOW Prophylaxis Master is intended for use in the following dental and periodontal applications:

- Removing supra and subgingival calculus deposits and stains from teeth
- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planing
- Releasing crowns, bridges, inlays, and posts as well as condensing gutta percha

- Plugging for amalgam condensation
- Amalgam burnishing
- Preparing, cleaning and irrigating root canals
- Cavity preparation
- Cementing inlays and onlays
- Retrograde preparation of root canals

The AIRFLOW Prophylaxis Master is intended for use in the cleaning and polishing of teeth by the projection of water, air, and dental powders onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth.
The AIRFLOW Prophylaxis Master can be used for the following cleaning procedures:

- Plaque removal for placement of sealants
- Surface preparation prior to bonding/cementation of inlays, onlays, crowns and veneers
- Surface preparation prior to placing composite restorations
- Effective plaque and stain removal for orthodontic patients
- Cleaning prior to bonding ortho brackets
- Cleaning implant fixture prior to loading
- Stain removal for shade determination
- Plaque removal prior to fluoride treatment
- Plaque and stain removal prior to whitening procedure

The AIRFLOW Prophylaxis Master is intended for use as an air-polisher in patients suffering from periodontal disease. The AIRFLOW Prophylaxis Master is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

The AIRFLOW One is intended for use in the cleaning and polishing of teeth by the projection of water, air, and dental powders onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth.
The AIRFLOW One can be used for the following cleaning procedures:

- Plaque removal for placement of sealants
- Surface preparation prior to bonding/cementation of inlays, onlays, crowns and veneers
- Surface preparation prior to placing composite restorations
- Effective plaque and stain removal for orthodontic patients
- Cleaning prior to bonding ortho brackets
- Cleaning implant fixture prior to loading
- Stain removal for shade determination
- Plaque removal prior to fluoride treatment
- Plaque and stain removal prior to whitening procedure

The AIRFLOW One is intended for use as an air-polisher in patients suffering from periodontal disease. The AIRFLOW One is indicated for the non-surgical removal of

subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

6. Summary of Technological Characteristics Compared to the Predicate Devices

The proposed devices and the predicate have similar technological characteristics. The overall design and functions of the proposed AIRFLOW Prophylaxis Master and AIRFLOW One are identical to those of the predicate AIR-FLOW MASTER PIEZON. The modifications made to the AIR-FLOW MASTER PIEZON to produce the AIR-FLOW Prophylaxis Master and the AIRFLOW One are limited to some improvements in terms of aesthetics and ergonomics.

The safety and effectiveness questions regarding the modifications to the AIR-FLOW MASTER PIEZON to produce the AIRFLOW Prophylaxis Master and the AIRFLOW One are whether the devices maintain their reliability and electrical safety characteristics and whether the use is adequately described within the instructions for use. These questions apply to both the proposed devices and the predicate. The proposed devices do not raise different questions of safety and effectiveness than the predicate.

Therefore, the proposed devices, AIRFLOW Prophylaxis Master and AIRFLOW One, meet substantial equivalence requirements with regards to the legally marketed predicate AIR-FLOW MASTER PIEZON (K110173 cleared on 04/07/2011).

A side-by-side comparison of the predicate device and the proposed devices is provided in Table 5-1 in the following page.

Table 5-1. Comparison Table for Determination of Substantial Equivalence

Substantial Equivalence Table					
Item for Comparison		**Proposed Device (AIRFLOW Prophylaxis Master)**	**Proposed Device (AIRFLOW One)**	**Predicate Device (AIR-FLOW MASTER PIEZON)**	**Variations**
REGULATORY INFORMATION	Name	AIRFLOW Prophylaxis Master	AIRFLOW One	AIR-FLOW MASTER PIEZON	N/A
	510(k) Number	Pending	Pending	K110173	N/A
	Predicates	K110173	K110173	K093000, K092289, K082791, K073284, K900709, K093723	N/A
	Product Code	ELC	KOJ	ELC	**Same** for AIRFLOW Prophylaxis Master. **Equivalent** for AIRFLOW One.
	Subsequent Product Codes	KOJ EJR	- EJR	EFB (now KOJ) EJR	**Same**
	Class	II	II	II	**Same**
	Combination Product	No	No	No	**Same**
	Regulation Number	872.4850	872.6080	872.4850	**Same** for AIRFLOW Prophylaxis Master. **Equivalent** for AIRFLOW One.
	Regulation Generic Name	Ultrasonic scaler	Airbrush	Ultrasonic scaler	
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 in conjunction with articulation paper. The device uses air-driven particles to roughen the surfaces of dental restorations. Uneven areas of the restorations are then identified by use of articulation paper"	"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** for AIRFLOW Prophylaxis Master. **Equivalent** for AIRFLOW One.
	Indications for use	The AIRFLOW Prophylaxis Master combines the functions of an ultrasonic scaler and air-polishing unit within a single chassis. The AIRFLOW Prophylaxis Master is intended for use in the following dental and periodontal applications: • Removing supra and subgingival calculus deposits and stains from teeth • Periodontal pocket lavage with		The AIR-FLOW MASTER PIEZON combines the functions of an ultrasonic scaler and air-polishing unit within a single chassis. The AIR-FLOW MASTER PIEZON is intended for use in the following dental and periodontal applications: • Removing supra and subgingival calculus deposits and stains from teeth • Periodontal pocket lavage with	**Same**

Substantial Equivalence Table					
Item for Comparison		**Proposed Device (AIRFLOW Prophylaxis Master)**	**Proposed Device (AIRFLOW One)**	**Predicate Device (AIR-FLOW MASTER PIEZON)**	**Variations**
		simultaneous ultrasonic tip movement • Scaling and root planing • Releasing crowns, bridges, inlays, and posts as well as condensing gutta percha • Plugging for amalgam condensation • Amalgam burnishing • Preparing, cleaning and irrigating root canals • Cavity preparation • Cementing inlays and onlays • Retrograde preparation of root canals --- The AIRFLOW Prophylaxis Master is intended for use in the cleaning and polishing of teeth by the projection of water, air, and dental powders onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth. The AIRFLOW Prophylaxis Master can be used for the following cleaning procedures: • plaque removal for placement of sealants • surface preparation prior to bonding/cementation of inlays, onlays, crowns and veneers • surface preparation prior to placing composite restorations • effective plaque and stain removal for orthodontic patients • cleaning prior to bonding ortho brackets • cleaning implant fixture prior to loading • stain removal for shade determination • plaque removal prior to fluoride treatment • plaque and stain removal prior to whitening procedure --- The AIRFLOW Prophylaxis Master is also intended for use as an air-polisher in patients suffering from periodontal disease. The	N/A --- The AIRFLOW One is intended for use in the cleaning and polishing of teeth by the projection of water, air, and dental powders onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth. The AIRFLOW One can be used for the following cleaning procedures: • plaque removal for placement of sealants • surface preparation prior to bonding/cementation of inlays, onlays, crowns and veneers • surface preparation prior to placing composite restorations • effective plaque and stain removal for orthodontic patients • cleaning prior to bonding ortho brackets • cleaning implant fixture prior to loading • stain removal for shade determination • plaque removal prior to fluoride treatment • plaque and stain removal prior to whitening procedure --- The AIRFLOW One is also intended for use as an air-polisher in patients suffering from periodontal disease. The AIRFLOW One is	simultaneous ultrasonic tip movement • Scaling and root planing • Releasing crowns, bridges, inlays, and posts as well as condensing gutta percha • Plugging for amalgam condensation • Amalgam burnishing • Preparing, cleaning and irrigating root canals • Cavity preparation • Cementing inlays and onlays • Retrograde preparation of root canals --- The AIR-FLOW MASTER PIEZON is intended for use in the cleaning and polishing of teeth by the projection of water, air, and dental powders onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth. The AIR-FLOW MASTER PIEZON can be used for the following cleaning procedures: • plaque removal for placement of sealants • surface preparation prior to bonding/cementation of inlays, onlays, crowns and veneers • surface preparation prior to placing composite restorations • effective plaque and stain removal for orthodontic patients • cleaning prior to bonding ortho brackets • cleaning implant fixture prior to loading • stain removal for shade determination • plaque removal prior to fluoride treatment • plaque and stain removal prior to whitening procedure --- The AIR-FLOW MASTER PIEZON is also intended for use as an air-polisher in patients suffering from periodontal disease. The AIR-	

Substantial Equivalence Table					
Item for Comparison		**Proposed Device (AIRFLOW Prophylaxis Master)**	**Proposed Device (AIRFLOW One)**	**Predicate Device (AIR-FLOW MASTER PIEZON)**	**Variations**
		AIRFLOW Prophylaxis Master is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.	indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.	FLOW MASTER PIEZON is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.	
TECHNOLOGICAL CHARACTERISTICS	Anatomical sites	Teeth and soft tissues in the mouth.	Teeth and soft tissues in the mouth	Teeth and soft tissues in the mouth.	**Same**
	Specific Treatment site	Supragingival and Subgingival	Supragingival and Subgingival	Supragingival and Subgingival	**Same**
	Contact duration	Limited ≤ 24 hours	Limited ≤ 24 hours	Limited ≤ 24 hours	**Same**
	Biocompatibility	Biocompatible	Biocompatible	Biocompatible	**Same**
	Patient Contacting Materials	Titanium COC PPSU EPDM Stainless Steel PEEK Hytrel SC969	- - - - Stainless Steel PEEK Hytrel SC969	Titanium COC PPSU EPDM Stainless Steel PEEK Hytrel SC969	**Same**
	Sterility	Provided non-sterile	Provided non-sterile	Provided non-sterile	**Same**
	Shelf life	Unrestricted	Unrestricted	Unrestricted	**Same**
	General purpose	Dental cleaning and periodontal (gum) therapy	Dental cleaning and periodontal (gum) therapy	Dental cleaning and periodontal (gum) therapy	**Same**
	Functions	Ultrasonic scaling and air-polishing	Air-polishing	Ultrasonic scaling and air-polishing	**Same**
	Mechanism of action	• Application of an ultrasonic vibrating scaler tip to the teeth • Projection of water/air/powder mixture	- • Projection of water/air/powder mixture	• Application of an ultrasonic vibrating scaler tip to the teeth • Projection of water/air/powder mixture	**Same**
	Electric power supply	• 100-240 VAC • 50-60Hz	• 100-240 VAC • 50-60Hz	• 100-240 VAC • 50-60Hz	**Same**
	Ultrasonic generator	EJ-120	N/A	EJ-097	The ultrasonic generator EJ-120 was cleared for marketing in K140990 (PIEZON 707 BIK and PIEZON 707 BIK LED).
	Ultrasound Max output power	8 W	N/A	8W (using the handpiece)	**Same**

Substantial Equivalence Table					
Item for Comparison		**Proposed Device (AIRFLOW Prophylaxis Master)**	**Proposed Device (AIRFLOW One)**	**Predicate Device (AIR-FLOW MASTER PIEZON)**	**Variations**
	Ultrasound Frequency	24 to 32 kHz	N/A	24 to 32 kHz	**Same**
	Operating Mode	Continuous Operation	Continuous Operation	Continuous Operation	**Same**
	Flow rate adjustment	Mechanical regulator	Mechanical regulator	Touch panel	**Equivalent**
	Water delivery system	• One irrigating liquid bottle for ultrasonic scaling treatment • Connection to external water supply for both ultrasonic scaling and air-polishing treatment	• One irrigating liquid bottle • Connection to external water supply	• One irrigating liquid bottle for ultrasonic scaling treatment • Connection to external water supply for air-polishing treatment	**Equivalent**
	Waterlines reprocessing	Integrated	Integrated	Manual	**Equivalent**
	Software	ES-087 ES-091 ES-125 ES-046	ES-087 ES-091 ES-125	ES-029-030 ES-035 ES-036A	**Equivalent**
	Foot pedal	Wireless or wired	Wireless or wired	Wired	**Equivalent**
	Components	• Control Unit • Powder chambers • Irrigation liquid bottle • Foot pedal • AIR-FLOW Handpiece • PERIO-FLOW Handpiece • PERIO-FLOW Nozzle marked • Piezon Handpiece LED • Instruments	• Control Unit • Powder chambers • Irrigation liquid bottle • Foot pedal • AIR-FLOW Handpiece • PERIO-FLOW Handpiece • PERIO-FLOW Nozzle marked	• Control Unit • Powder chambers • Irrigation liquid bottle • Foot pedal • AIR-FLOW Handpiece • PERIO-FLOW Handpiece • PERIO-FLOW Slim Nozzle • Piezon Handpiece LED • Instruments	The PERIO-FLOW Nozzle Marked was cleared for marketing in K171174 (PERIO-FLOW nozzle).
	Prophylaxis Powders for Use with System	• PERIO (Glycine) • SOFT (Glycine) • CLASSIC (Sodium Bicarbonate) • PLUS (Erythritol)	• PERIO (Glycine) • SOFT (Glycine) • CLASSIC (Sodium Bicarbonate) • PLUS (Erythritol)	• PERIO (Glycine) • SOFT (Glycine) • CLASSIC (Sodium Bicarbonate) • PLUS (Erythritol)	**Same**

7. Summary of Non-Clinical Performance Testing as Basis for Substantial Equivalence

Testing was performed to verify compliance of the AIRFLOW Prophylaxis Master and AIRFLOW One with the following standards:

- ISO 14971: 2007, “Medical devices - Application of risk management to medical devices”
- ISO 17664: 2004, “Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices”
- ISO 17665-1: 2006, “Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices”
- ANSI/AAMI ST79: 2010 / A1:2010 / A2:2011 / A3:2012 / A4:2013, “Comprehensive guide to steam sterilization and sterility assurance in health care facilities”
- ANSI/AAMI ES60601-1: 2005/(R)2012/A1:2012, “C1:2009/(R)2012 and A2:2010/ (R) 2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)”
- IEC 60601-1-2: 2014, “Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests”
- IEC 80601-2-60:2012, “Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment”
- IEC 60601-1-6: 2013, “Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability”
- IEC 62304: 2015, “Medical device software - Software life cycle processes”
- ISO 15223-1: 2016, “Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements”
- ISO 10993-1: 2009, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]”
- ISO 7405: 2008, Dentistry - “Evaluation of biocompatibility of medical devices used in dentistry [Including: Amendment 1 (2013)]”
- ISTA 2A: 2011, “Packaged-Products 150lb (68 kg) or less”

The results of this testing confirm that the AIRFLOW Prophylaxis Master and AIRFLOW One are safe and effective for the indications for use described in Section 4.

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

Based on the information and supporting documentation provided in the premarket notification, the EMS AIRFLOW Prophylaxis Master and AIRFLOW One are substantially equivalent to the cited predicate device. Testing demonstrates that the EMS AIRFLOW Prophylaxis Master and AIRFLOW One fulfill prospectively defined design and performance specifications.