



Food and Drug Administration  
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February 3, 2016

E.M.S. ELECTRO MEDICAL SYSTEMS S.A.  
Ms. Suzanne Fassio-Hardy  
Regulatory Affairs Manager  
Chemin de la Vuarpillière 31  
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Switzerland

Re: K151912  
Trade/Device Name: AIR-FLOW handy 3.0 PLUS  
Regulation Number: 21 CFR 872.4200  
Regulation Name: Dental handpiece and accessories  
Regulatory Class: I  
Product Code: EFB  
Dated: December 23, 2015  
Received: December 28, 2015

Dear Ms. Fassio-Hardy:

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" (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.

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,

 Tina Kiang  
-S

for 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

## Section 4: Indications for Use Statement

510(k) Number (if known): k151912

Device Name: AIR-FLOW handy 3.0 PLUS

Indications for Use:

The AIR-FLOW handy 3.0 PLUS Dental Handpiece is a dental handpiece intended for use in the cleaning and polishing of teeth by the projection of a mixture of water, air, and EMS prophylaxis powder onto the tooth surface. The device removes soft deposits and areas of discoloration and can be used to prepare teeth for dental procedures such as the placement of composite fillings, porcelain inlays, and laminate veneers. The device can be used to clean implant abutments and to clean teeth prior to treatments such as shade matching, fluoridation, and bleaching. The device can also be used to degrease crowns and bridges prior to placement and clean fixed bands and brackets on orthodontic appliances.

The AIR-FLOW handy 3.0 PLUS is intended for patients suffering from periodontal disease.

The AIR-FLOW handy 3.0 PLUS is indicated for the non-surgical removal of subgingival plaque in pockets up to 4 mm after initial periodontal treatment.

Prescription Use  (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use  (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**510(k) Summary**  
**for the**  
**E.M.S. Electro Medical Systems SA**  
**AIR-FLOW handy 3.0 PLUS**

Prepared February 2, 2016

**1. SUBMITTER/510(K) HOLDER**

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**3. DEVICE NAME**

Proprietary Name: AIR-FLOW handy 3.0 PLUS

Common/Usual Name: Dental handpiece

Classification Name: Dental handpiece and accessories

**4. PREDICATE DEVICES**

The following legally marketed medical devices have been identified as predicate:

- E.M.S. Electro Medical Systems S.A., AIR-FLOW handy 3.0 PERIO (K132480)
- E.M.S. Electro Medical Systems S.A., AIR-FLOW handy 3.0 (K132478)

## 5. DEVICE DESCRIPTION

The proposed *AIR-FLOW handy 3.0 PLUS* device is similar in design and materials to the predicates *AIR-FLOW handy 3.0* (K132478) and *AIR-FLOW handy 3.0 PERIO* (K132480). The proposed *AIR-FLOW handy 3.0 PLUS* device and the predicates connect to a standard turbine connection on a dental operative unit and deliver a mixture of water, air, and prophylaxis powder to a treatment site. The handpiece component of the proposed *AIR-FLOW handy 3.0 PLUS* (PLUS) is to be commercialized as an additional optional accessory to the predicate *AIR-FLOW handy 3.0 PERIO* (PERIO) handpiece component. Therefore, the proposed PLUS and the predicate PERIO share the same EMS reference number FT-221#. The purpose for adding this additional PLUS handpiece is so that the patients can have both supragingival treatments and subgingival treatments by the same *AIR-FLOW PERIO* prophylaxis powder that is previously cleared in *AIR-FLOW MASTER* (K082791) and thus create more convenience for the users. There are no changes to the powder in this submission.

The *AIR-FLOW handy 3.0* (STANDARD) and the proposed device, *AIR-FLOW handy 3.0 PLUS* (PLUS) handpieces, have the same air and water ports to enable supragingival use.

The difference between the proposed PLUS and the predicate PERIO is the handpiece, which has the same body, powder chamber and handpiece body with the only difference being the nozzle. The geometric shape of the integrated nozzle of the PLUS handpiece is relatively thin and slim which enables the supragingival use and the subgingival use in pockets up to 4 mm after initial periodontal treatment. The integrated nozzle of PLUS handpiece has no direct contact with the subgingival shallow pocket. The separate slim nozzle of PERIO that has direct contact with the subgingival pocket enables the subgingival use in pockets up to 5mm after initial periodontal treatment.

The PLUS handpiece should not be used with the STANDARD powder chamber. To prevent this, a different connector is used so that it can only be used with the PERIO powder and PERIO powder chamber. The PLUS handpiece uses the same PERIO polishing powder as the PERIO handpiece.

The proposed *AIR-FLOW handy 3.0 PLUS* device is therefore substantially equivalent to the previously FDA-cleared *AIR-FLOW handy 3.0 PERIO* (K132480) and *AIR-FLOW handy 3.0* (K132478).

## **6. INTENDED USE**

The AIR-FLOW handy 3.0 PLUS is a dental handpiece intended for use in the cleaning and polishing of teeth by the projection of a mixture of water, air, and EMS prophylaxis powder onto the tooth surface. The device removes soft deposits and areas of discoloration and can be used to prepare teeth for dental procedures such as the placement of composite fillings, porcelain inlays, and laminate veneers. The device can be used to clean implant abutments and to clean teeth prior to treatments such as shade matching, fluoridation, and bleaching. The device can also be used to degrease crowns and bridges prior to placement and clean fixed bands and brackets on orthodontic appliances.

The AIR-FLOW handy 3.0 PLUS is intended for patients suffering from periodontal disease.

The AIR-FLOW handy 3.0 PLUS is indicated for the non-surgical removal of subgingival plaque in pockets up to 4 mm after initial periodontal treatment.

## **7. PRINCIPLES OF OPERATION**

The principles of operation of the proposed PLUS hand-held device are identical to the predicates PERIO and STANDARD. Both the proposed and parent devices are hand-held devices that connect to a standard turbine connection on a dental operative unit and deliver a mixture of water, air and prophylaxis powder to a treatment site.

## **8. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES**

This new device, *AIR-FLOW handy 3.0 PLUS*, represents a modification to the cleared *AIR-FLOW Handy 3.0 PERIO* to include the supragingival cleaning capability of the *AIR-FLOW handy 3.0*. The proposed *AIR-FLOW handy 3.0 PLUS* and the predicates all connect to the same standard turbine connection on a dental operative unit, and all deliver a mixture of water, air, and dental powder to a treatment site.

**Table 1: Comparison Table for Determination of Substantial Equivalence for AIR FLOW handy 3.0 PLUS**

Item for Comparison	EMS AIR-FLOW handy 3.0 PLUS Proposed	EMS AIR-FLOW handy 3.0 K132478	EMS AIR-FLOW handy 3.0 PERIO K132480
Indications for Use	<p>The AIR-FLOW handy 3.0 PLUS Dental Handpiece is a dental handpiece intended for use in the cleaning and polishing of teeth by the projection of a mixture of water, air, and EMS prophylaxis powder onto the tooth surface. The device removes soft deposits and areas of discoloration and can be used to prepare teeth for dental procedures such as the placement of composite fillings, porcelain inlays, and laminate veneers. The device can be used to clean implant abutments and to clean teeth prior to treatments such as shade matching, fluoridation, and bleaching. The device can also be used to degrease crowns and bridges prior to placement and clean fixed bands and brackets on orthodontic appliances.</p> <p>The AIR-FLOW handy 3.0 PLUS is intended for patients suffering from periodontal disease.</p> <p>The AIR-FLOW handy 3.0 PLUS is indicated for the non-surgical removal of subgingival plaque in pockets up to 4 mm after initial periodontal treatment.</p>	<p>The AIR-FLOW handy 3.0 Dental Handpiece is a dental handpiece intended for use in the cleaning and polishing of teeth by the projection of a mixture of water, air, and EMS prophylaxis powder onto the tooth surface. The device removes soft deposits and areas of discoloration and can be used to prepare teeth for dental procedures such as the placement of composite fillings, porcelain inlays, and laminate veneers. The device can be used to clean implant abutments and to clean teeth prior to treatments such as shade matching, fluoridation, and bleaching. The device can also be used to degrease crowns and bridges prior to placement and clean fixed bands and brackets on orthodontic appliances.</p>	<p>The AIR-FLOW handy 3.0 PERIO is intended for patients suffering from periodontal disease.</p> <p>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.</p>

Item for Comparison	EMS AIR-FLOW handy 3.0 PLUS Proposed	EMS AIR-FLOW handy 3.0 K132478	EMS AIR-FLOW handy 3.0 PERIO K132480
Treatment Site	Supragingival and Subgingival	Supragingival	Subgingival
Compatible Prophylaxis Powders	Perio (Glycine)	Soft (Glycine)	Perio (Glycine)
Function	Air-polishing		
Mechanism of action	Projection of water/air/powder mixture		
Operational characteristics	Mode: continuous operation		
	<ul style="list-style-type: none"> <li>• Service pressure to the turbine connection: Water <ul style="list-style-type: none"> <li>o 1 to 2.2 bar (1000-2200 hPa) with a service flow of 50-80 ml/min.</li> </ul> </li> <li>• Service pressure to the turbine connection: Air <ul style="list-style-type: none"> <li>o Static pressure 2.7 to 3.5 bar (2700-3500 hPa)</li> </ul> </li> </ul>		
	<ul style="list-style-type: none"> <li>• Operating conditions: +10°C to +40°C, 30% to 75% relative humidity,</li> <li>• 700 hPa to 1060 hPa air pressure,</li> </ul>		
	Storage conditions: <ul style="list-style-type: none"> <li>• +5°C to +40°C,</li> <li>• 5% to 85% relative humidity,</li> <li>• 500 hPa to 1060 hPa air pressure</li> </ul> Transport conditions: <ul style="list-style-type: none"> <li>• -10°C to +40°C (ventilated) or 60°C (non ventilated),</li> <li>• 75% relative humidity,</li> <li>• min. 700hPa air pressure</li> </ul>		

The differences between the *AIR-FLOW handy 3.0 PLUS* (PLUS) and *AIR-FLOW handy 3.0 PERIO* (PERIO) and the *AIR-FLOW handy 3.0* (STANDARD) are as follows:

- The PLUS handpiece component goes on the same already approved body as the PERIO
- The PLUS handpiece and body use the same components as the PERIO ones
- The PLUS devices uses the same AIR-FLOW prophylaxis powder as the PERIO one
- The PLUS handpiece component combines the clinical indications of the PERIO with the removable nozzle and the STANDARD handpieces to enable supragingival and subgingival use, but with a connector to ensure that it can only be used with the PERIO body, and not with the STANDARD body
- The PLUS handpiece does not have a disposable nozzle, unlike the PERIO
- The geometric shape of the integrated nozzle of PLUS handpiece is relatively thin and slim which enables the supragingival use and the subgingival use in pockets up to 4 mm after initial periodontal treatment. The separate slim nozzle

of PERIO enables the subgingival use in pockets up to 5mm after initial periodontal treatment.

- Powder and water outlets are identical to the STANDARD to enable supragingival use.

Testing has demonstrated that the proposed *AIR-FLOW handy 3.0 PLUS* fulfills the prospectively defined performance specifications. The similarities in intended use, operational characteristics, and technological characteristics lead to a conclusion of substantial equivalence between the proposed and predicate devices. Side-by-side comparisons of the predicate devices and the proposed device are provided in Tables 1, 2, and 3 at the end of this section.

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

Testing was performed to verify compliance of the *AIR-FLOW handy 3.0 PLUS* with the following standards:

- ANSI/AAMI ST79: 2010/A4:2013, “Comprehensive guide to steam sterilization and sterility assurance in health care facilities”
- ANSI/AAMI/ISO 17665-1:2013 “Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices”
- IEC 62366 (2007+AMD1:2014 CSV), “Medical devices - Application of usability engineering to medical devices”
- ISO 10993-1 (2009/Cor1:2010), “Biological evaluation of medical devices - Part 1: Evaluation and testing”
- ISO 13485 (2003) + CORR. 1: 2009, “Medical Devices: Quality Management Systems-Requirements for Regulatory Purposes”
- ISO 14971 (2007), “Medical Devices-Risk Management, Part 1: Application of Risk Analysis to Medical Devices”
- ISO 15223-1 (2012), “Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: general requirements”
- ISO 17664 (2004), “Sterilization of Medical Devices – Information to be provided by the Manufacturer for the Processing of Resterilizable Medical Devices”
- ISTA 2A (2011), “ISTA Preshipment Testing Procedures- Combination Tests for Packaged-Products 150 lb (68 kg) or Less”

Additionally, comparison testing of the subject device and the predicate device as used with currently available EMS powders was performed. This test suite includes powder flow rate, powder residue, powder working time and cleaning efficiency. The test suite results passed.

The results of this testing confirm that the *AIR-FLOW handy 3.0 PLUS* is as safe and as effective for the intended use described in Section 6.

The results of this testing confirm that the *AIR-FLOW handy 3.0 PLUS* is substantially equivalent to the predicates.

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

No clinical testing was conducted for this submission.

## 11. SUMMARY OF OTHER INFORMATION

No other information is available.

## 12. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

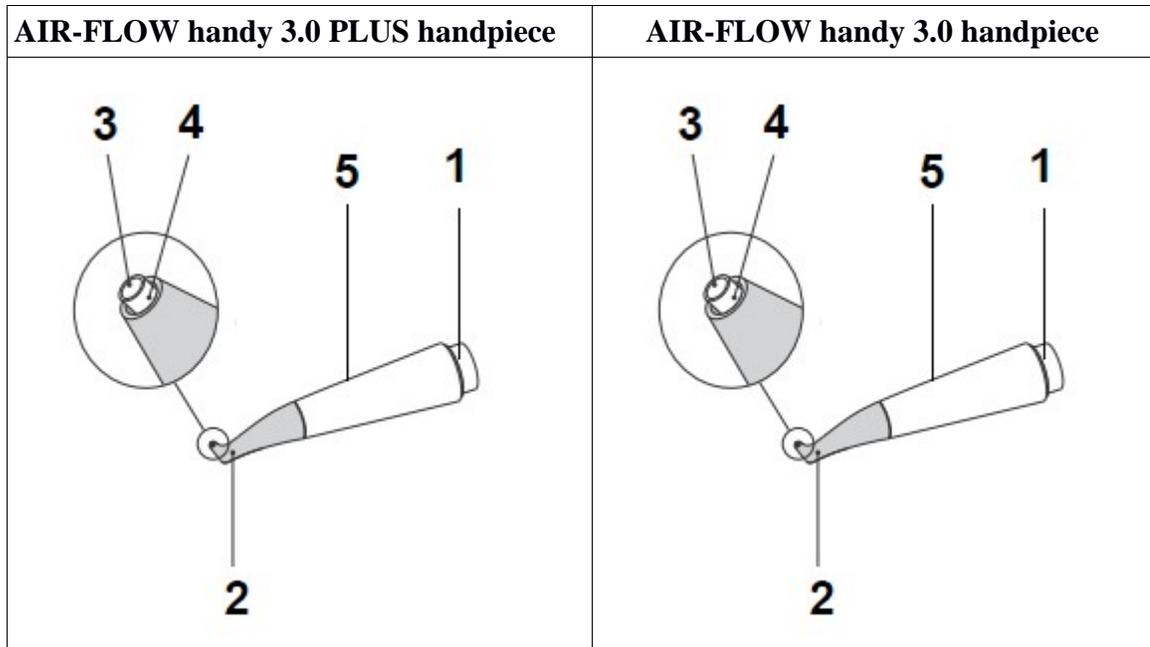
Based on the information and supporting documentation provided in the premarket notification, the *AIR-FLOW handy 3.0 PLUS* is substantially equivalent to the cited predicate devices. . The operational characteristics and overall design of the proposed *AIR-FLOW handy 3.0 PLUS* are identical to those of the predicate *AIR-FLOW handy 3.0* and *AIR-FLOW handy 3.0 PERIO*. A comparison of the intended use, principles of operation, and technological characteristics of the proposed and predicate devices support the indications for use for the proposed PLUS device. This *AIR-FLOW handy 3.0 PLUS* device combine the capabilities of the *AIR-FLOW handy 3.0* and the *AIR-FLOW handy 3.0 PERIO* to enable supragingival and subgingival use.

**Table 2: Comparison of AIR-FLOW handy 3.0 PLUS and predicate AIR-FLOW handy 3.0 PERIO**

Item #	AIR-FLOW handy 3.0 PLUS Components	AIR-FLOW handy 3.0 PERIO Components	Compare
1	Handpiece	Handpiece	Different
2	Body	Body	Same
3	Powder chamber	Powder chamber	Same
4	Powder chamber cap	Powder chamber cap	Same
5	Cord adapter	Cord adapter	Same
6	Powder outlet port	Powder outlet port	Different

7	Water outlet port	Water outlet port	Different
8	Cap ring	Cap ring	Same
9	Air tube	Air tube	Same
10	Air/powder tube	Air/powder tube	Same
11	O-rings for handpiece connection	O-rings for handpiece connection	Same
12	EasyClean	EasyClean	Same
13	Nozzle	PERIO-FLOW Nozzle	Different
14	No nozzle remover	Nozzle remover	Different

**Figure 1: Comparison of Handpieces: AIR-FLOW handy 3.0 PLUS and predicate AIR-FLOW handy 3.0 handpieces**



**Table 3: Comparison of Handpieces: AIR-FLOW handy 3.0 PLUS and predicate AIR-FLOW handy 3.0**

Item #	AIR-FLOW handy 3.0 PLUS Components	AIR-FLOW handy 3.0 Components	Compare
1	Connector	Connector	Different
2	Nozzle	Nozzle	Same
3	Powder outlet port	Powder outlet port	Same
4	Water outlet port	Water outlet port	Same
5	Handpiece body	Handpiece body	Same