



Food and Drug Administration
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E.M.S. Electro Medical Systems S.A.
Suzanne Fassio-Hardy
Regulatory Affairs Manager -- Dental
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SWITZERLAND

September 11, 2017

Re: K171189
Trade/Device Name: AIR-FLOW PLUS Prophylaxis powder
Regulation Number: 21 CFR 872.6030
Regulation Name: Oral Cavity Abrasive Polishing Agent
Regulatory Class: Class I
Product Code: EJR
Dated: June 20, 2017
Received: June 20, 2017

Dear Suzanne 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 (DICE) 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 (DICE) 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,


Mary S. Runner -S

for Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K171189

Device Name
AIR-FLOW PLUS Prophylaxis Powder

Indications for Use (Describe)

The AIR-FLOW PLUS Prophylaxis Powder is indicated for use with EMS dental handpieces for cleaning and preparation of teeth.

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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510 (K) SUMMARY FOR AIR-FLOW PLUS PROPHYLAXIS POWDER (K171189)

Date: May 10, 2017

I. SUBMITTER/ 510(K) HOLDER

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II. DEVICE NAME

Proprietary Name: AIR-FLOW PLUS Prophylaxis Powder
Common/Usual Name: Prophylaxis Powder

Classification Name: Oral cavity abrasive polishing agent (872.6030)

Device Class: I

Product Code: EJR

III. PREDICATE DEVICES

The AIR-FLOW PLUS Prophylaxis Powder is a substantially equivalent new version of the legally marketed 510(k) *exempt* powders E.M.S PERIO Powder (predicate, *exempt* but included in K082791 cleared on 02/18/2009) and E.M.S. Soft Powder (reference device *exempt* but included in K110173 cleared on 04/07/2011). The proposed device is submitted via premarket notification [510(k) pathway] because the addition of CPC will exceed the limitations of the exemptions listed in Sec. 872.9 (b); since CPC has preservative properties, it is considered to be a different fundamental technology.

Neither the predicate device nor reference device have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The proposed AIR-FLOW PLUS Prophylaxis Powder is an erythritol powder containing 0.05% Cetyl Pyridinium Chloride (CPC) as a preservative. This prophylaxis powder is intended to be used with all currently available EMS dental handpieces for AIR-FLOW and PERIO-FLOW treatments. The addition of CPC is to preserve the powder from bacterial contamination by humidity and microorganisms when the container is opened. Clinical studies have not been conducted to demonstrate that the presence of CPC in this device results in improved clinical outcomes.

The principle of operation of the proposed AIR-FLOW PLUS Prophylaxis Powder is identical to predicate and reference device powders; the powder is mixed with air and water in the dental handpiece nozzle to create a mechanically abrasive stream used in polishing procedures.

V. INDICATIONS FOR USE

The AIR-FLOW PLUS Prophylaxis Powder is indicated for use with EMS dental handpieces for cleaning and preparation of teeth.

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

The proposed AIR-FLOW PLUS Prophylaxis Powder is intended to be used with all currently available EMS AIR-FLOW and PERIO-FLOW dental handpieces.

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

- Used in EMS AIR-FLOW devices
- Powder is mixed with water and air

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

- The proposed powder material is erythritol with CPC, the predicate powders are Glycine
- Reduced grain size of powder

The safety and effectiveness questions regarding the material differences are biocompatibility and performance within the dental handpiece devices. These questions apply to both the new device and the predicate and so the new device does not raise different questions of safety and efficacy. Therefore, the proposed device, AIR-FLOW PLUS Prophylaxis Powder, meets substantial equivalence requirements with regards to the legally marketed 510(k) *exempt* powders PERIO Prophylaxis Powder.

VII. PERFORMANCE DATA

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

Shelflife testing:

- 24 months real time aging

Biocompatibility testing:

The biocompatibility evaluation for the AIR-FLOW PLUS Prophylaxis Powder 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 change of material (ingredients and size) does not impact the performance of the powder, functional testing was completed on the proposed device and the predicate devices. Since the requirements for a subgingival powder differ from the requirements of a supra gingival powder, comparison testing is separated into two reports as described below.

Subgingival Applications [comparison to predicate powder (PERIO)]

Comparison testing between the PERIO (predicate) and PLUS (proposed) powders included a cleaning test and an abrasivity test.

The performance of the powder is measured by the capability to clean a metallic plate and by the abrasivity of the powder itself. The cleaning test compares the ability of the powders' to remove paint from a metal plate and the abrasivity test compares the powders' erosion of a known material (PEEK). The results of these two comparison tests show that the two powders are equivalent with respect to performance (abrasivity test) however the PLUS powder (proposed) is more efficient with respect to cleaning.

Supragingival Applications [comparison to reference device powder (SOFT)]

Comparison testing consists of cleaning efficiency test between the SOFT (reference device) and PLUS (proposed) powders, as well as several other marketed supra gingival powders (CLASSIC, COMFORT, and SOFT). The test is performed using an automated test bench to clean a painted metal surface. Cleaning efficiency is a calculation of flow-rate and time to clean. The results of this comparison test show that the PLUS (proposed) powder is more efficient than the SOFT (reference device), however the cleaning efficiency is similar to other marketed powders.

All tests were successfully performed and all acceptance criteria were met, thus confirming that AIR-FLOW PLUS Prophylaxis Powder satisfactorily meet requirements. No new questions of safety and effectiveness were identified during review of Risk Management documentation or during execution of comparison testing.

VIII. CONCLUSIONS

Based on the information and supporting documentation provided in the premarket notification, the AIR-FLOW PLUS Prophylaxis Powder is substantially equivalent to the cited predicate and reference devices. Testing demonstrates that the AIR-FLOW PLUS Prophylaxis Powder fulfills prospectively defined design and performance specifications.