K073284

510(k) Summary
for
AIR-FLOW MASTER STANDARD

1. SPONSOR

EMS ELECTRO MEDICAL SYSTEMS SA
Ch. de la Vuarpillière 31
CH - 1260 Nyon
Switzerland

DEC 1 4 2007

Contact: Suzanne Fassio-Hardy
Date Prepared: November 20, 2007

2. DEVICE NAME

Proprietary Name:	AIR-FLOW MASTER STANDARD
Common/Usual Name:	Airbrush/Dental handpiece
Classification Name:	Airbrush and accessories/Dental handpiece and accessories

3. PREDICATE DEVICES

- EMS Electro Medical Systems SA, AIR-FLOW S2, K900709

4. DEVICE DESCRIPTION

The AIR-FLOW MASTER STANDARD is an air-polishing unit containing an operating unit, air/water pressure powered handpiece cords, powder chambers, AIR-FLOW handpieces, prophylaxis powders, multifunction footpedal and connections for external water and air supply. The operating unit of the AIR-FLOW MASTER STANDARD regulates the water and air/powder flow and selection of the prophylaxis powder chamber (Working Mode). The multifunction footpedal controls the operation of the AIR-FLOW handpieces. Upon installation, the AIR-FLOW MASTER STANDARD operating unit is connected to the external water and air supply.

Prior to use, the prophylaxis powder is loaded into the powder chamber and the chamber fixed to the operating unit. The AIR-FLOW handpiece is inserted into the air pressure powered handpiece cord and a powder nozzle is attached to the end of the AIR-FLOW handpiece. The operating unit is switched on and the air/powder flow and the Working Mode are adjusted on the control panel. When the operating unit is switched on, the

powder chambers are under pressure. Air enters the powder chamber of the operating unit where it mixes with the prophylaxis powder. The air/powder mixture leaves the powder chamber and enters the handpiece cord. When the multifunction footpedal is pressed, the air pressure of the handpiece cord is activated and allows the air/powder mixture to be delivered to the AIR-FLOW handpiece for treatment. The air/powder mixture exits the distal end of the AIR-FLOW handpiece through the powder nozzle where it is enveloped by a water spray and directed onto the tooth surface.

5. INTENDED USE

The AIR-FLOW MASTER STANDARD is an air-polishing unit 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 device can also 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

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The overall design of the proposed AIR-FLOW MASTER STANDARD is identical to the design of the parent AIR-FLOW S2 described in K900709. Both devices include an operational unit, powder chambers, AIR-FLOW handpiece, and the prophylaxis powder. They both contain controls for delivery of the air/water/powder mixture and provide nozzles for delivery. Both of the devices allow for control of the powder/air mixture delivery via a footpedal.

The technical modifications made to the parent device to produce the AIR-FLOW MASTER STANDARD are limited to removal of the ultrasonic functionality, updating the design of the operating unit, AIR-FLOW handpiece, and powder chambers, and the addition of controlling software. In addition, the prophylaxis powder accessories available were expanded to include the AIR-FLOW Soft prophylaxis powder and expand the offerings in the previously-cleared AIR-FLOW Prophylaxis Powder product line.

The changes made to the parent device to produce the AIR-FLOW MASTER STANDARD are minor and do not represent modifications to the indications for use, operating principles, or the fundamental scientific technology of the device. Testing was conducted to confirm that the proposed AIR-FLOW MASTER STANDARD meets established performance specifications. Based on the above discussion and the comparison chart on the following page, EMS Electro Medical Systems S.A. believes that the proposed AIR-FLOW MASTER STANDARD is substantially equivalent to the parent air-polishing unit, AIR-FLOW S2 cleared for marketing in the U.S. (K900709).

Comparison Chart for Determination of Substantial Equivalence

Item for Comparison	AIR-FLOW MASTER STANDARD Proposed	AIR-FLOW S2 K900709
Intended Use	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.	
Function	Air polisher	Air polisher Ultrasonic scaler
Cleaning and Preparatory Action	Projection of air/powder/water mixture	
Operational Unit	Control of air/powder/water delivery	Same
Footpedal Activation	Yes	Same
Water and Air Supply	External	Same
Powder Location	Powder Chamber	Same
Prophylaxis Powder	AIR-FLOW Classic AIR-FLOW Soft	AIR-FLOW Prophylaxis powder
Dental Handpiece	AIR-FLOW handpiece*	AIR-FLOW handpiece Piezon handpiece (ultrasonic)
Sterilization Process	AIR-FLOW handpiece and powder nozzle: steam	AIR-FLOW handpiece and powder nozzle: steam

** Minor upgrades from the original handpiece (AIR-FLOW S2); identical to AIR-FLOW Handy2 (K022119)*

7. PERFORMANCE TESTING

The appropriate design verification and design validation activities were conducted to address the potential risks identified in the Risk Analyses for the modifications made to the parent device, AIR-FLOW S2. These activities included electrical safety testing, electromagnetic compatibility testing, biocompatibility assessment, and functional testing. The results confirmed that the AIR-FLOW MASTER STANDARD is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2007

(EMS SA) Electro Medical Systems
C/O Ms. Susan M. Bonapace
Regulatory Associate
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K073284
Trade/Device Name: AIR–FLOW MASTER STANDARD
Regulation Number: 872.6080
Regulation Name: Airbrush
Regulatory Class: II
Product Code: EFB, KOJ
Dated: November 20, 2007
Received: November 21, 2007

Dear Ms. Bonapace:

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.

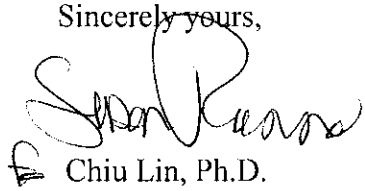
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: AIR-FLOW MASTER STANDARD

Indications for Use:

The AIR-FLOW MASTER STANDARD is an air-polishing unit 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.

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- plaque removal prior to fluoride treatment
- plaque and stain removal prior to whitening procedure

Prescription Use ___X___ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

K073281