FEB 18 2009

510(k) Summary
for the
E.M.S. ELECTRO MEDICAL SYSTEMS SA
EMS AIR-FLOW MASTER

1. SPONSOR

E.M.S. ELECTRO MEDICAL SYSTEMS SA
Ch. de la Vuarpillière 31
CH - 1260 Nyon
Switzerland

Contact Person: Suzanne Fassio-Hardy
Telephone: 022 994 47 00

Date Prepared: February 5, 2009

2. DEVICE NAME

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

3. PREDICATE DEVICES

- Electro Medical Systems S.A., AIR-FLOW MASTER STANDARD (K073284)

4. INTENDED USE

The EMS AIR-FLOW MASTER is intended for patients suffering from periodontal disease and peri-implantitis.

The EMS AIR-FLOW MASTER is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

5. DEVICE DESCRIPTION

The EMS AIR-FLOW MASTER is a dental air-polishing unit containing an operating unit, air pressure powered handpiece cords, powder chambers, an AIR-FLOW MASTER AIR-FLOW handpiece and a PERIO-FLOW handpiece, AIR-FLOW

CLASSIC, SOFT and PERIO Prophylaxis powder, multifunction footpedal and connections for external water and air supply. The EMS AIR-FLOW MASTER is a modification of the EMS AIR-FLOW MASTER STANDARD that was cleared for marketing as K073284 for cleaning of teeth using a specially designed nozzle to deliver a mixture of water, air, and dental powders to a treatment site. The proposed EMS AIR-FLOW MASTER is supplied with a flexible thermoplastic nozzle that is used for subgingival cleaning of periodontal pockets.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed EMS AIR-FLOW MASTER is similar in design and materials to the predicate EMS AIR-FLOW MASTER STANDARD. The proposed device is supplied with a flexible thermoplastic nozzle that allows the device to be used for subgingival cleaning of periodontal pockets.

Both the proposed EMS AIR-FLOW MASTER and predicate EMS AIR-FLOW MASTER STANDARD are intended for the cleaning of teeth using a specially designed nozzle to deliver a mixture of water, air, and dental powders to a treatment site. However, the proposed AIR-FLOW MASTER is supplied with a flexible, thermoplastic nozzle, which allows the indications for use for the device to be extended to include subgingival cleaning of periodontal pockets.

Both the proposed EMS AIR-FLOW MASTER and the predicate EMS AIR-FLOW MASTER STANDARD dental air-polishing unit consist of an operating unit, air pressure powered handpiece cords, powder chambers, handpieces, prophylaxis powder, multifunction footpedal and connections for external water and air supply. The AIR-FLOW MASTER PERIO-FLOW handpiece is specially designed for subgingival cleaning of periodontal pockets.

Testing provided in this premarket notification includes electrical safety, electromagnetic compatibility, performance testing and clinical data. Test results demonstrate that the EMS AIR-FLOW MASTER fulfills the prospectively defined performance specifications and can be used safely and effectively for subgingival cleaning. The similarities in intended use, operational characteristics, and functional technological characteristics between the AIR-FLOW MASTER and the AIR-FLOW MASTER STANDARD lead to a conclusion of substantial equivalence between the proposed and predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

E.M.S Electro Medical Systems S.A.
C/o Dr. Cynthia J. M. Nolte
Senior Regulatory Affairs Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

FEB 18 2009

Re: K082791
Trade/Device Name: EMS AIR-FLOW MASTER
Regulation Number: 872.6080
Regulation Name: Airbrush
Regulatory Class: II
Product Code: EFB
Dated: February 5, 2009
Received: February 6, 2009

Dear Dr. Nolte:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting 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): K082791

Device Name: EMS AIR-FLOW MASTER

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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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082791