OCT 20 2009

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

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: October 20, 2009

2. DEVICE NAME

Proprietary Name:	EMS AIR-FLOW handy PERIO
Common/Usual Name:	Dental handpiece
Classification Name:	Dental handpiece and accessories

3. PREDICATE DEVICES

- Electro Medical Systems S.A., AIR-FLOW MASTER (K082791)
- Electro Medical Systems S.A., AIR-FLOW handy 2 (K022119)

4. INTENDED USE

The EMS AIR-FLOW handy PERIO is intended for patients suffering from periodontal disease.

The EMS AIR-FLOW handy PERIO 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 handy PERIO is a modification of the AIR-FLOW handy 2 Dental Handpiece that was cleared for marketing as K022119. The proposed EMS AIR-FLOW handy PERIO handpiece is supplied with a flexible thermoplastic nozzle and a prophylaxis powder (cleared for use with the AIR-FLOW MASTER, subject of K082791) that are specially designed to permit use of the device for the non-surgical removal of subgingival plaque.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed EMS AIR-FLOW handy PERIO is similar in design and materials to the AIR-FLOW handy 2 Dental Handpiece and the PERIO-FLOW handpiece component of the AIR-FLOW MASTER. Both the proposed EMS AIR-FLOW handy PERIO and the predicate AIR-FLOW handy 2 connect to a standard turbine connection on a dental operative unit. The PERIO-FLOW handpiece functions as a component of the standalone AIR-FLOW MASTER air polishing unit.

Both the proposed and predicate handpieces deliver a mixture of water, air, and dental powder to a treatment site. The proposed EMS AIR-FLOW handy PERIO handpiece is supplied with a nozzle and prophylaxis powder that allows the device to be used for the nonsurgical removal of subgingival plaque. The predicate AIR-FLOW MASTER is indicated for both supragingival and subgingival use. The predicate AIR-FLOW handy 2 Dental Handpiece is restricted to supragingival applications.

Testing conducted demonstrates that the EMS AIR-FLOW handy PERIO fulfills the prospectively defined performance specifications. The similarities in intended use, operational characteristics, and functional technological characteristics between the AIR-FLOW handy PERIO, the AIR-FLOW handy 2, and the PERIO-FLOW handpiece component of the AIR-FLOW MASTER lead to a conclusion of substantial equivalence between the proposed and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

OCT 20 2009

EMS Electro Medical Systems S.A.
C/O Cynthia J.M. Nolte, Ph.D., RAC
Senior Regulatory Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K092289
Trade/Device Name: EMS AIR-FLOW Handy PERIO
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: July 24, 2009
Received: July 29, 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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/Reporta Problem/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 Small Manufacturers, International and Consumer Assistance 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,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092289

Indications for Use

510(k) Number (if known):

Device Name: EMS AIR-FLOW handy PERIO

Indications for Use:

The EMS AIR-FLOW handy PERIO is intended for patients suffering from periodontal disease.

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

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)

R S Betz DDS for Dr. K. Mulvey
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092289