

JUL 25 2002

K022119

**510(k) Summary
for
Electro Medical Systems SA
AIR-FLOW[®] handy 2 Dental Handpiece**

1. SPONSOR

ELECTRO MEDICAL SYSTEMS SA
Chemin de la Vuarpilliere 31
CH-1260 Nyon
Switzerland

Contact Person: Suzanne Fassio-Hardy
Date Prepared: June 28, 2002

2. DEVICE NAME

Trade/Proprietary Name: EMS AIR-FLOW[®] handy 2
Common/Usual Name: Dental handpiece
Classification Name: Dental handpiece and accessories

3. INTENDED USE

The EMS AIR-FLOW[®] handy 2 is intended for use in the cleaning and polishing of teeth by the projection of a mixture of water, air, and bicarbonate 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.

4. DEVICE DESCRIPTION

The AIR-FLOW[®] handy 2 is a modified version of the AirFlow[®] handy previously cleared under K991857. As with the original AirFlow[®] handy device, the proposed AIR-FLOW[®] handy 2 is a turbine-adaptable air polisher that consists of a hand-held

device containing air and water lines, powder chamber with cap, and an AIR-FLOW[®] nozzle called the AIR-FLOW[®] handpiece.

Both the original and the modified device function by connecting to a standard turbine connection of the dental unit, which supplies air and water. The AIR-FLOW[®] handy 2 is activated when the AIR-FLOW[®] handy 2 Handpiece is fixed to the turbine connection and the dental unit pedal is pressed. Air enters the proximal end of the device and into the powder chamber where it is mixed with the AIR-FLOW[®] handy 2 powder. The air/powder mixture leaves the powder chamber and exits the distal end of the device through the AIR-FLOW[®] handpiece orifice where the air/powder mixture is enveloped by a water spray and directed onto the tooth surface.

5. BASIS FOR SUBSTANTIAL EQUIVALENCE

The AIR-FLOW[®] handy 2 has the same intended use as the original AirFlow[®] handy, which was determined to be substantially equivalent to marketed devices under 510(k) K991857.

The AIR-FLOW[®] handy 2 utilizes the same technique as the original AirFlow[®] handy. The AIR-FLOW[®] handy 2 offers several improved features including the following:

- the air and powder tubing inside the handpiece is straight instead of curved, which reduces the probability of clogging and facilitates cleaning
- the handpiece is longer, facilitating handling and rotation of the handpiece by the user during the treatment
- a filter and sieve have been added to the air and water lines offering protection of the one-way valve of the connector and the powder chamber. The filters and sieves protect the powder chamber and the one-way valves by preventing any passage of impurities that circulate in the water and air canals. The filter in the air canal prevents back-flow of powder and dissipates humidity by vaporization of any drops of water, which prevents clogging
- the powder chamber capacity has been increased to 23 g from 18 g reducing the number of refills necessary during treatments

6. TESTING

Verification and validation of the device design requirements were performed to provide confirmation that all design requirements were met. The final project monitoring results documented that all verification and validation activities required by the risk analysis were performed and all requirements of the design specifications were met.



JUL 25 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Electro Medical Systems SA
C/O Ms. Mary McNamara-Cullinane
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K022119

Trade/Device Name: EMS Air-Flow Handy 2 Dental Handpiece
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: June 28, 2002
Received: July 1, 2002

Dear Ms. Cullinane:

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.

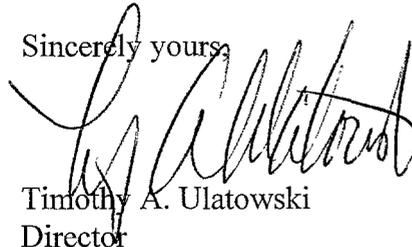
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022119

Device Name: AIR-FLOW® handy 2 Dental Handpiece

Indications For Use:

The EMS AIR-FLOW® handy 2 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 bicarbonate 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.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K022119

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)