OCT 7 1999

K991857

APPENDIX B

Modified 510(k) Summary

510(k) Summary
for
AirFlow handy

1. SPONSOR

Electro Medical Systems SA
Ch. Vuarpillière 31
1260 Nyon
SWITZERLAND

Contact Person: Daniel Rochat, Operational Director
Telephone: 41-22-994 47 18, 41-22-994 47 00

Date Prepared: September 9, 1999

2. DEVICE NAME

Proprietary Name: AirFlow handy
Common/Usual Name: Dental handpiece
Classification Name: Dental handpiece and accessories

3. PREDICATE DEVICES

- AirFlow SII (K900709)
- Prophyflex 2, Model 2012 (K973876)

4. DEVICE DESCRIPTION

The AirFlow handy is a hand-held device containing air and water lines, powder chamber with cap, and AirFlow nozzle. The device connects to a standard turbine tube which supplies air and water. When the AirFlow handy is connected to the turbine tube and the turbine is activated, an air/powder stream enveloped by a water spray is generated which can be directed onto the tooth surface for cleaning and polishing.

5. INTENDED USE

The AirFlow handy is a dental handpiece intended for use in the cleaning and polishing of teeth by the projection of water, air, and bicarbonate powder onto the tooth surface. The device removes soft deposits and areas of discoloration and can be used to clean teeth prior to dental procedures which require a clean tooth surface such as the placement of composite fillings, inlays, and laminate veneers.

The device can also be used to clean the following:

- implant abutments and teeth prior to treatments such as shade matching, fluoridation, and bleaching
- crowns and bridges
- fixed bands and brackets prior to placement on orthodontic appliances.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Both the proposed device and the substantially equivalent devices are intended for use in the cleaning and polishing of teeth. Unlike the predicate AirFlow SII, the proposed device does not function as a scaler.

The operational principle of the proposed device is identical to that of the AirFlow SII and the Prophyflex 2. The cleaning and polishing action is produced by the projection of air, water, and bicarbonate powder onto the tooth surface. The proposed device is supplied with a fixed nozzle or a rotating nozzle with a tip angle of 90° or 120°. The fixed AirFlow nozzle is identical to the nozzle used for the predicate AirFlow SII. The rotating AirFlow nozzles are identical to the predicate AirFlow SII except for minor design modifications to permit the tip to rotate. The rotating nozzle is also similar to the Prophyflex II nozzle.

The AirFlow handy differs from the AirFlow SII in size and in the location of the powder chamber. The proposed AirFlow handy is smaller than the AirFlow SII, and, like the Prophyflex 2, the powder chamber has been incorporated into the body of the device.

The differences between the proposed and predicate devices are restricted to minor differences in size, design, and materials and do not impact the safety or effectiveness of the device.

7. PERFORMANCE TESTING

Testing was performed to support a minimal reuse life of 130 treatments, which corresponds to 15 hours of use. Connection-integrity testing demonstrated that the connection between the turbine adaptor and the dental unit remained intact when subjected to air pressures of 10 bar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 1999

Cynthia J.M. Nolte, Ph.D., RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K991857
Trade Name: AirFlow Handy
Regulatory Class: I
Product Code: EFB
Dated: September 9, 1999
Received: September 10, 1999

Dear Dr. Nolte:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K991857

Device Name: AirFlow handy

Indications for Use:

The AirFlow handy is a dental handpiece intended for use in the cleaning and polishing of teeth by the projection of water, air, and bicarbonate powder onto the tooth surface. The device removes soft deposits and areas of discoloration and can be used to clean teeth prior to dental procedures which require a clean tooth surface such as the placement of composite fillings, inlays, and laminate veneers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991857

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)