K041141

JUN 16 2004

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

JUN 1 6 2004

Dentsply International
Mr. Jeffery P. Lehn
Director of Corporate Compliance and Regulatory Affairs
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404

Re: K041141
Trade/Device Name: Dentsply Cavitron Jet Wave air Polishing Prophylaxis System
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: April 28, 2004
Received: April 30, 2004

Dear Mr. Lehn:

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 (301) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,

for 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 STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): **K041141**

Device Name: JET WAVE™ SYSTEM

Indications for Use:

The JET WAVE™ SYSTEM is indicated for air polishing procedures including the removal of a variety of extrinsic stains; general prophylaxis; and cleaning tooth surfaces prior to bonding and sealant procedures.

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 Runyon

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

510(k) Number: K041141