K033812

FEB 23 2004

510(k) Summary
for
SIROAIR L Air Scaler

1. SPONSOR

Sirona Dental Systems GmbH
Farbrikstrasse 31
64625 Bensheim
Germany

Contact Person: Fritz Kolle
Regulatory Manager

Date Prepared: December 5, 2003

2. Device Name

Proprictary Name:	SIROAIR L Air Scaler
Common/Usual Name:	Air-powered Scaler
Classification Name:	Dental handpiece and accessories

3. Predicate Devices

W&H Corsair Scaler (K944714)

4. INTENDED USE

The Sirona Dental Systems SIROAIR L Air Scaler is an air-powered scaler intended for use in calculus removal (subgingival and supragingival).

5. DEVICE DESCRIPTION

The Sirona SIROAIR L Scaler (SIROAIR) consists of a handpiece, quick-action coupling and accessories for changing and cleaning the instrument tips. The SIROAIR handpiece connects to an air-driven handpiece hose on a dental operative unit. The power delivered to the handpiece is adjusted via a control ring located on the handpiece.

Three types of couplings are available. Two types contain a halogen lamp and a control ring to adjust the water flow. The third type lacks the lamp and has a fixed water flow.

A variety of instrument tips (SIROTIPS) are available that are designed for specific dental procedures and to access particular areas of the mouth.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

Both the proposed SIROAIR and the predicate Corsair device are air-powered scalers used for removal of calculus deposits during dental cleaning procedures. The overall designs of the proposed SIROAIR and predicate Corsair Scaler are similar. Both the proposed and predicate scalers offer a variety of instrument tips specifically designed for performing the indicated dental procedures and accessing teeth in specific areas of the mouth.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 3 2004

Sirona Dental Systems GmbH
C/O Ms. Mary McNamara-Cullinanc
Medical Devices Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K033812
Trade/Device Name: SIROAIR L Air Scaler
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: December 5, 2003
Received: December 9, 2003

Dear Ms. McNamara-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.

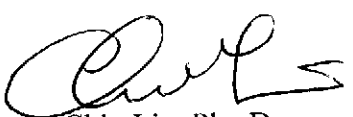
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), 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,



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

K033812

510(k) Number (if known):

Device Name: SIROAIR L Air Scaler

Indications for Use:

The SIROAIR L Air Scaler is an air-powered scaler intended for use in calculus removal (subgingival and supragingival).

(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033812

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

(Optional Format 1-2-96)