K033640

DEC 12 2003

510(k): Device Modification
510(k) Summary
for
Siroson L and Sirosonic L Ultrasonic Scalers

1. SPONSOR

Sirona Dental Systems GmbH
Farbrikstrasse 31
64625 Bensheim
Germany

Contact Person: Fritz Kolle
Regulatory Manager

Date Prepared: November 18, 2003

2. Device Name

Proprietary Name: Siroson and Sirosonic L Ultrasonic Scalers
Common/Usual Name: Ultrasonic Scaler
Classification Name: Ultrasonic Scaler

3. Predicate Devices

EMS Piezon Master 600 (K022328)

4. INTENDED USE

The Sirona Sirosonic L and Siroson L are an ultrasonic scalers intended for use in the following dental and periodontal applications:

- Calculus removal (supragingival and subgingival)
- Retrograde root treatment
- Endodontics
- Insertion of inlays
- Micropreparation-(cavity preparation)
- Periodontology

5. DEVICE DESCRIPTION

The proposed Sirona ultrasonic scalers consist of the ultrasonic handpiece, instrument tips, and control unit, which is part of the Sirona C8+ Dental Operative Unit. The Ultrasonic Scalers are electrically operated scalers driven by a piezo oscillator at 25 to 32 kHz. The piezo oscillator is located in the handpiece and the control/generator unit is located in the C8+ Dental Operative Unit. Both devices include a lamp located in the hose and a spray water controller. A number of optional tips are supplied with the Sirona ultrasonic scalers.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The overall design of the Sirona Ultrasonic Scalers is similar to the design of the Piezon® Master 600. Both these devices include a dental handpiece and ultrasonic generator. They all contain software, which controls delivery of the ultrasonic power, and include various tip configurations for the differing dental procedures.

On both the proposed and predicate Piezon 600 scaler units, the ultrasonic power can be adjusted via a rotary knob on the control unit and delivery of the ultrasonic energy is via a foot control.

The Sirona Scalers and the Piezon® Master 600 allow the operator to select among different operating modes. These modes have different ultrasonic power ranges to assist the operator in maintaining the ultrasonic power within an appropriate range for specific applications.

Both systems allow for irrigation using a bottled water source or an external water source. Irrigation is controlled from the handpiece using a control ring for the Sirona Scalers and a flow regulator for the Piezon® Master 600. Irrigation flow for the Sirona Scalers can also be controlled using a rotary knob on the C8+ dentist's element.

Based on the comparison of intended use and technical features, Sirona Dental Systems believes that the Siroson L and the Sirosonic L are substantially equivalent to the Piezon® Master 600. The proposed and predicate devices have the same general intended use and principles of operation. The overall design of the proposed and predicate devices is similar.

7. PERFORMANCE TESTING

The appropriate design verification and design validation activities were conducted to address the potential risks identified in the Hazard Analysis. These activities included electrical safety testing and electromagnetic compatibility testing. The results confirm that the Siroson L and the Sirosonic L are safe and effective for their intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2003

Sirona Dental Systems GmbH
C/O Ms. Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K033640
Trade/Device Name: Siroson L and Sirosonic L Ultrasonic Scalers
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: November 18, 2003
Received: November 20, 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. 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) you may obtain. 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,

Chiu S. Lin, PhD
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): K033640

Device Name: Siroson L and the Sirosonic L Ultrasonic Scalers

Indications for Use:

The Sirona Dental Systems Siroson L and the Sirosonic L are ultrasonic scalers intended for use in the following dental and periodontal applications:

- Calculus removal (subgingival and supragingival)
- Retrograde root treatment
- Endodontics
- Insertion of inlays
- Micropreparation (cavity preparation)
- Periodontology

(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: K033640

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

(Optional Format 1-2-96)