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**510(k) Summary  
for  
Sirona Dental Systems  
PerioScan**

**1. SPONSOR**

Sirona Dental Systems GmbH  
Fabrikstrasse 31  
D-64625 Bensheim  
Germany

Contact Person: Fritz Kolle  
Telephone: 49 6251 16 32 94

Date Prepared: July 25, 2007

**2. DEVICE NAME**

Proprietary Name: PerioScan  
Common/Usual Name: Ultrasonic Scaler  
Classification Name: Ultrasonic Scaler

**3. PREDICATE DEVICE**

Sirona PerioScan Ultrasonic Scaler (K050354) and SiroSonic L Ultrasonic Scaler (K033640).

**4. INTENDED USE**

The Sirona Dental Systems PerioScan is an ultrasonic scaler that aids in the recognition of calculus and intended for use in the following dental and periodontal applications:

- Aiding in subgingival calculus detection
- Calculus removal (subgingival and supragingival)
- Retrograde root treatment
- Endodontics
- Insertion of inlays
- Micropreparation (cavity preparation)

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- Periodontology

**5. DEVICE DESCRIPTION**

The Sirona PerioScan Ultrasonic Scaler consists of a table-top unit with two detachable irrigant bottles with caps (lids), a footswitch, an ultrasonic handpiece, hoses and connectors, a variety of optional tips for different dental procedures, and a tool for attaching the tips to the handpiece.

The PerioScan unit provides ultrasonic scaler therapy as described in the above indications and detection-aid-function for recognition of subgingival calculus.

The table-top unit houses the operator input and controls for the supply of irrigant, cooling liquid and light for the handpiece. The device is connected to 120V mains power supply, and it may be connected to a mains water supply. The irrigant for the handpiece is drawn from the two internal liquid containers or from the mains water supply. The handpiece is connected to the table-top unit via a hose and can be deposited in the claw. A footswitch with two single foot pedals is used to control the handpiece. The PerioScan handpiece is an electrically operated scaler driven by a piezo ceramics. The handpiece includes an illumination and two signal LEDs and a Spray water controller, all located in the hose.

PerioScan switches between detection and scaling operation mode, if selected, using the footswitch. Detection of subgingival calculus is signaled through an illuminator ring and operator display. Additionally a signal tone may be emitted if desired.

**6. BASIS FOR SUBSTANTIAL EQUIVALENCE**

The overall design of the Sirona PerioScan Ultrasonic Scaler with detection-aid-function for recognition of subgingival calculus is similar to the design of the Sirona PerioScan Ultrasonic Scaler (PerioScan Basic) with no detection-aid-function. Both of 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 PerioScan Scaler (PerioScan Basic) units, the ultrasonic power can be adjusted on the control unit and delivery of the ultrasonic energy is via a foot control. Both devices allow the operator to select among different therapy operating modes. These modes have different ultrasonic power ranges to

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assist the operator in maintaining the ultrasonic power within an appropriate range for specific applications. Both Systems allow for irrigation using two internal containers (small and large) or an external water source. Irrigation flow is controlled by handpiece, operator's panel and footswitch for the Sirona PerioScan with detection-aid-function as well as for the PerioScan with no such function.

The PerioSonic handpiece used with the Sirona PerioScan with detection-aid-function is the SiroSonic L handpiece with minor alterations for enabling detection capability and signaling.

Clinical studies and testing have been performed that validate detection-aid-function for recognition of subgingival calculus for the proposed PerioScan device.

Based on the comparison of intended use and technical features, Sirona Dental Systems believes that the PerioScan with detection-aid-function for recognition of subgingival calculus is substantially equivalent to the PerioScan with no such function. 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. The detection function aids the practitioner in recognizing of subgingival calculus who assesses the diagnosis result and the subsequent therapy.



FEB 14 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Fritz Kolle  
Quality Management/Regulatory Affairs  
Sirona Dental Systems GmbH  
Fabrikstrasse 31  
D-64625 Bensheim  
GERMANY

Re: K072107  
Trade/Device Name: PerioScan Model D 3496  
Regulation Number: 21 CFR 872.4850  
Regulation Name: Ultrasonic Scaler  
Regulatory Class: II  
Product Code: ELC  
Dated: February 1, 2008  
Received: February 4, 2008

Dear Mr. Kolle:

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.

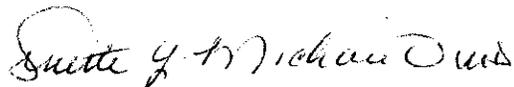
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.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

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510(k) Number (if known):

Device Name: PerioScan

Indications for Use:

The Sirona Dental Systems PerioScan Ultrasonic Scaler is an ultrasonic scaler that aids in the recognition of calculus and intended for use in the following dental and periodontal applications:

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

Prescription Use X  
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(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

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