K083344

510(k) Summary
for
Sirona Dental Systems
HELIODENT Plus

DEC 23 2008

1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstrasse 31
D-64625 Bensheim
Germany

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

Date Prepared: August 25, 2008

2. DEVICE NAME

Proprietary Name:	HELIODENT Plus
Common/Usual Name:	Unit, X-Ray, Extraoral with Timer
Classification Names:	Extraoral source x-ray system

3. PREDICATE DEVICE

Sirona HELIODENT DS (K960819) and Progeny Preva Dental X-Ray System (K043092)

4. INTENDED USE

The HELIODENT Plus is an extraoral X-Ray source System intended to be used for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.

5. DEVICE DESCRIPTION

The HELIODENT Plus is an extraoral source dental X-ray system intended for intraoral imaging. X-rays are produced using a multi-pulse generator with a selectable tube voltage of 60 and 70 kV and a tube current of 7 mA. A microprocessor-controlled timer allows for consistent and accurate exposure control,

and an adjustable arm allows for easy positioning. The system can be used either with conventional film or a digital imaging system. Basic settings of exposure times are pre-programmed and may be selected by buttons.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

Based on the comparison of intended use, construction, and technical features, Sirona Dental Systems believes that the HELIODENT Plus is substantially equivalent to the HELIODENT DS (K960819) and Progeny Preva Dental X-Ray System (K043092). The proposed and predicate devices have the same intended use and principles of operation. The overall designs of the proposed and predicate devices are similar. Technical specifications of the HELIODENT Plus are the same or very similar to those of the predicate devices. All devices generate the X-ray radiation using a multi-pulse generator source. The characteristics of the X-ray tube, including tube voltage, tube current, focal spot, focal length and X-ray filtration, and the X-ray exposure times are all within equivalent ranges.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sirona Dental Systems GmbH
% Mr. Olaf Teichert
Third Party Reviewer
TUV SUD America, Inc.
1775 Old Hwy. 8 N.W., Suite 104
NEW BRIGHTON MN 55112-1891

DEC 23 2008

Re: K083344
Trade/Device Name: HELIODENT Plus
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: December 9, 2008
Received: December 11, 2008

Dear Mr. Teichert:

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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K083344

Device Name: HELIODENT Plus

Indications for Use:

The HELIODENT Plus is an extraoral X-Ray source System intended to be used for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.

Prescription Use ___X___ 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 NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083344