K072665

3 510(k) Summary

OCT 3 2007

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Contact Person	Marc Fieber
Date Prepared	June 9, 2007
Trade Name	SuniRay 5.2
Common Name	SuniRay
Classification name	LLZ, Picture Archiving and Communications System
Classification Code	21 CFR 892.2050
Classification Number	Class II
Classification Panel	Radiology
Equivalent Device	XRAY VISION, FDA registration number K983111
Reason for the 510(k)	New device

This 510(k) submission was prepared according to the requirements of 21CFR §807.87.

3.1 Device Description

SuniRay is a software package designed to work with Standard PC compatible computers capable of running a Microsoft Windows operating system. The software is designed to be a fully functional digital radiograph scanning, archiving, electronic transmission and diagnostic review system. SuniRay permits the acquisition of images directly from commercially available scanners, digital cameras, intra-oral cameras, intra-oral X-ray sensors, panoramic X-ray machines, etc.

Once an image has been converted into digital format, SuniRay permits the user to easily organize and archive digital radiographs, images, and other patient related files.

SuniRay provides tools that permit the user to enhance images and place markers as well as annotations on radiographs to aid in the diagnostic process. The image enhancements provided by this software package utilize industry standard algorithms that do not result in the alteration of an image's or a radiograph's content. Once imported into SuniRay, the original image content is never changed. Image enhancements are stored separately from the original image.

Unlike a direct digital system, SuniRay does not control the X-ray taking system and does not generate radiographs directly from the physical world (SuniRay processes images and radiographs produced from other devices and physical media). SuniRay only permits enhancing radiographs for diagnostic purposes and does not allow the introduction of false data or the modification of the original images and radiographs in any way.

To facilitate enhanced correlation of information with images, SuniRay permits direct association of customized information with an image. Using those associations the user is able to relate doctor information, patient's information, applied procedures, etc. with an image.

Electronic transmission capabilities are provided so that images can be sent to specialists and insurance companies for claim processing and diagnostic review.

The images and the database containing information related to images, doctors, and patients can be shared among multiple installations of the software.

SuniRay uses any standard Windows-compatible printers to produce print-outs of images. These print-outs are intended for purposes of patient information only and not for diagnostic purposes.

In order to create patient information material, the software supports handing over image data and patient information to the programs Microsoft Word and PowerPoint. The documents prepared this way are intended for purposes of patient information only and not for diagnostic purposes.

As one type of annotation, SuniRay provides the possibility to place forms roughly shaped like dental implants. This function is not intended to replace detailed planning. It rather serves as a draft tool.

3.2 Intended Use

Uses for SuniRay in the dental industry are as follows:

- Organize and archive radiographs and patient related files
- Facilitate sharing and transmission of information between doctors, other applications and other computers
- Place markers and annotations radiographs for diagnostic purposes
- Allows users to dimension radiographs based on dimensions of X-ray sensors or reference objects.
- Provides image-processing tools such as sharpening, colorizing, resizing, etc. (none of which physically alter images).
- Permits sending of data by email.

The target group for using SuniRay for diagnostic purposes will be the doctor/dentist population. This software is primarily used to store a patient's imaging data (i.e. radiographs) in a form compatible with today's networked online practice management software. This software may also be used to transmit radiographs to specialists who will be treating the patient or the insurance company for approval of procedure and etc.

The intended use for SuniRay does not mention additional ways of sending data note in the intended uses for XRAY VISION such as client/server, ftp, phone and floppy disk. As this is a limitation, this difference is not considered to be critical.
Moreover, the intended use for XRAY VISION mentions the electronic transmission of images to insurance companies or specialists which is not included for SuniRay. We consider this point to be included in sending data by email and therefore do not mention it explicitly as an intended use for SuniRay.

3.3 Technological Characteristics

SuniRay is a "software only"-system, which will be delivered on CD-ROM / DVD and installed by service engineers.

The technological characteristics of SuniRay are:

- Utilization of the TWAIN interface standard to acquire images from imaging devices (scanners, digital cameras, intra-oral cameras, intra-oral X-ray sensors, panoramic X-ray machines, etc.).
- Utilizes standard image processing algorithms to improve image contrast, sharpness and quality.
- Utilizes standard image file formats for the storage and retrieval of images.
- Electronic transmission media consists of:
    - Email: Attachments utilized to transfer files via standard internet email.
    - Disk: Standard PC file I/O.
- Utilizes standard markers and annotations to draw attention to problem areas in an image (ellipse, arrow, text, freehand line, rectangles, etc).

Comparison of technological characteristics		
	XRAY VISON	SuniRay
1	Utilization of the TWAIN interface standard to acquire images from imaging devices (e.g. flatbed scanners, digital cameras, intra-oral cameras, etc.).	Utilization of the TWAIN interface standard to acquire images from imaging devices (e.g. scanners, digital cameras and intra-oral cameras, intra-oral X-ray sensors, panoramic X-ray machines, etc.).
2	Utilizes standard image processing algorithms to improve image contrast, sharpness and quality.	Utilizes standard image processing algorithms to improve image contrast, sharpness and quality.
3	Electronic transmission media consists of: ▪ Telephone: Common I/O and TAPI interface supported for transferring images and files over conventional phone lines. ▪ FTP: The standard Internet file transfer protocol. ▪ Client/Server: Standard Internet transfer method for sending files via Internet client-server connections. ▪ Email: MIMI attachments utilized to transfer files via standard Internet email. ▪ Disk: Standard PC file I/O.	Electronic transmission media consists of: ▪ Email: Attachments utilized to transfer files via standard internet email. ▪ Disk: Standard PC file I/O.
4	Archiving utilizes a knowledge base for recording the location and filename used to store files related to a patient.	-
5	Utilizes standard markers and annotations to draw attention to problem areas in an image (ellipse, arrow, text, freehand line, dots, rectangles, etc.).	Utilizes standard markers and annotations to draw attention to problem areas in an image (ellipse, arrow, text, freehand line, rectangles, etc.).
6	Industry standard encryption algorithms used for ensuring data integrity and secrecy.	-
7	Duplication of physical X-rays for use in sending radiographs to remote sites to ensure that the original radiographs are not lost or damaged by conventional parcel service.	-

The technological characteristics of XRAY VISION and SuniRay differ in marginal aspects:

- Row 3: SuniRay does not directly provide functionality for transferring files between computers. It rather relies on standard functionality provided by the Windows operating system and standard hardware.
- Row 4: SuniRay does not provide the ability to archive arbitrary references to files. For improved safety, it rather keeps patient related files in its own data store.
- Row 6 SuniRay does not provide cryptographic functionality. In the context of SuniRay, cryptography is relevant for two purposes:
  - Protection of data against unauthorized manipulation.
  - Encryption of image data in emails.

  In the first case, SuniRay adheres to standard image file formats to support interoperability. Ensuring data integrity is considered to be in the scope of the user's computer system administration.
  In the second case, multiple email encryption standards for securing emails exist, such as X.509 or PGP. The selection of the most appropriate method cannot be anticipated, since it depends on the cryptographic standard used by the user's communication partner. The user can select from a broad variety of dedicated cryptographic extensions for standard mail clients supporting his method of choice.
- Row 7: The print outs produced by SuniRay are considered to be used for patient information only and not for diagnostic purposes. For diagnostic purposes, digital copies of radiographic images are far more reliable.

3.4 General Safety and Effectiveness Concerns

The software is intended to be used by appropriately trained dentists. The software labeling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the software.
Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, orangedental GmbH & Co. KG adheres to recognized and established industry practice and standards.

3.5 Conclusion

SuniRay is designed to be a fully functional digital radiograph scanning, archiving, electronic transmission and diagnostic review system. SuniRay permits the acquisition of images directly from commercially available scanners, digital cameras, intra-oral cameras, intra-oral X-ray sensors, panoramic X-ray machines, etc.

Unlike a direct digital system, SuniRay does not control the X-ray taking system and does not generate radiographs directly from the physical world. SuniRay only permits enhancing radiographs for diagnostic purposes and does not allow the introduction of false data or the modification of the original images and radiographs in any way.

The potential hazards have been studied and controlled as part of the product development process. This includes risk analysis, test and design considerations, and planned verifications and validation testing processes.

The system has been shown to be substantially equivalent to the predicate device, and no new issues of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT 3 2007

Orangedental GmbH & Co., KG
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV SÜD America
1775 Old Hwy 8 NW, Ste 104
NEW BRIGHTON MN 55112-1891

Re: K072665
Trade/Device Name: SuniRay
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 19, 2007
Received: September 21, 2007

Dear Mr. Preiss:

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 (Premarket Approval), 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). 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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2 Indications for Use

510(k) Number (if known): -

Device Name: SuniRay

Indication for Use:

Uses for SuniRay in the dental industry are as follows:

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Prescription Use: **YES** AND/OR Over-The-Counter Use: **NO**
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072665