K070219

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 7 2007

Device Name

Trade Name	SuniRay II Digital Radiography System
Classification Name	Digital Extraoral Source X-Ray System
Common Name	Digital X-Ray

Classification

Device	Class II
Panel	Radiology
Procode	MUH
Reference	21 CFR 872.1800

Registration Number

3003952803

Sponsor Name and Address

Suni Medical Imaging, Inc.
6840 Via Del Oro
San Jose, CA 95119

Manufacturer Name and Address

Suni Medical Imaging, Inc.
6840 Via Del Oro
San Jose, CA 95119

Reason for Pre-Market Notification

New design

Equivalent Legally Marketed Device

K021718	Suni Intraoral Imaging System

Indications for Use:

The SuniRay II Digital Radiography System is used to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.

510(k) Summary of Safety and Effectiveness

The Suni SuniRay II Digital Radiography System ("System") will produce real time digital intra-oral images with a reduction in X-ray dosages as compared to film. The System accomplishes this by replacing X-ray film with an electronic sensor that captures the X-ray photons and converts the photons to an electronic signal which in turn is captured in a computer for viewing, manipulating, storing, and outputting (printing or Email).

The System consists of two sensor versions (designated as #1 & #2 sizes; equivalent to dental film sizes), an attached USB electronics box that controls the sensor and interfaces to the computer USB port. The System also includes software drivers that control the USB electronics box, and a Graphical User Interface (GUI) that allows the user access to the data and control functions of the System.

The GUI used with the device was designed by Apteryx, Inc. who holds 510(k) K983111 for their product. Apteryx is responsible for both product validation and GMP compliance. The SuniRay II System software utilizes the Windows XP environment.

The System sensors are in two formats. The #2 size is a larger sensor typical of the European format and the # 1 size is an intermediate size. The sensors consist of a CMOS type integrated circuit, and a high resolution scintillator screen that converts the photons from the X-rays into visible light, which is then acquired by the CMOS imaging integrated circuit. The sensors are encapsulated with a three-foot cable that is connected to the USB electronics box.

The USB electronics box plugs into a computer USB port via a supplied USB cable. The USB electronics box contains the support and control circuitry for the sensor and allows for data communications with the computer. The USB electronics box contains all necessary circuits for sensor data acquisition as well as memory for firmware control of the CMOS X-ray sensor and USB. The USB electronics box communicates with the computer under control of a specific device driver that is active with the GUI.

The System software functions on three levels: (1) The computer operating system (Microsoft Windows) controls the computer, user interface, and file structure; (2) Primary control of the sensor and bus functions is achieved by proprietary software and is either embedded firmware or in non user accessible drivers; and (3) A Graphical User Interface (GUI) allows the user to control the x-ray function, control of the sensor data acquisition, and image viewing, manipulation and output. Examples of the GUI include image capture, enhanced viewing features (zoom, pan, colorize, contrast/brightness, comparative analysis, etc) image organization, and storage.

The System meets the requirements of EN 60601 for safety and electromagnetic compatibility.
For this Pre-Market Notification, similarities and changes made to this System from the predicate are summarized in Section 8.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Suni Medical Imaging, Inc.
% Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Underwriters Laboratories, Inc.
455 E. Trimble Road
SAN JOSE CA 95131

FEB 7 2007

Re: K070219
Trade/Device Name: SuniRay II Digital Radiography System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: January 19, 2007
Received: January 23, 2007

Dear Mr. Christensen:

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

Indications for Use

510(k) Number (if known): ~~Not assigned~~ K070219

Device Name: SuniRay II Digital Radiography System

Indications for Use:

The SuniRay II Digital Radiography System is used to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070219