DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Suni Medical Imaging, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

November 4, 2016

Re: K162585
Trade/Device Name: SuniIQ Digital Radiography System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: October 26, 2016
Received: October 27, 2016

Dear Mr. Job:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162585

Device Name
SuniIQ Digital Radiography System

Indications for Use *(Describe)*
The SuniIQ 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

2. 510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DATE PREPARED	November 4, 2016
APPLICANT	Suni Medical Imaging, Inc. 6840 Via Del Oro, Suite #160 San Jose, CA 95119 www.suni.com Tel: (408) 227-6698
OFFICIAL CORRESPONDENT	Al Bettencourt Suni Medical Imaging, Inc. 6840 Via Del Oro, Suite #160 San Jose, CA 95119 Al.Bettencourt@suni.com Tel: (408) 337-0573 Fax: (408) 227-9304
TRADE NAME	SuniIQ Digital Radiography System
COMMON NAME	Digital Extraoral Source X-Ray System
MODEL NUMBERS	400-1321 SuniIQ Size 1 400-1322 SuniIQ Size 2
DEVICE CLASSIFICATION	Name: Extraoral source x-ray system Regulation No: 21 CFR §872.1800 Product Code: MUH Class: II Panel: Radiology
PREDICATE DEVICE	SuniRay II Digital Radiography System – K070219

SUBSTANTIALLY EQUIVALENT TO:

The SuniIQ Digital Radiography System is substantially equivalent in intended use and technological features to the SuniRay II Digital Radiography System (K070219).

SUMMARY OF SIMILARITIES / DIFFERENCES:

The SuniIQ Digital Radiography system shares the same design features as the predicate device and does not introduce any new technological characteristics. Following are the shared features:

Both devices convert x-rays to digital images using an indirect x-ray detector:

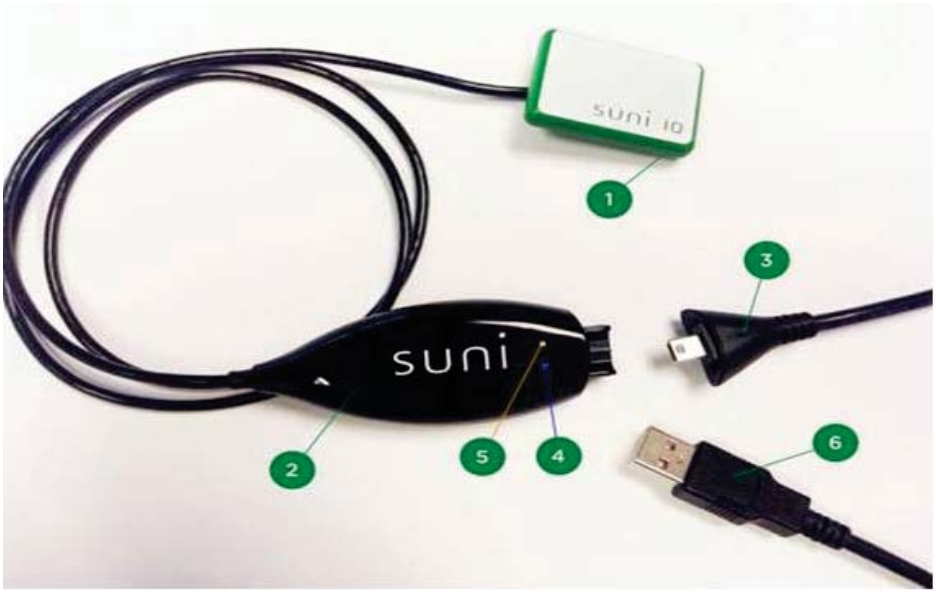
- The scintillator converts x-ray energy into visible light in proportion to the x-ray energy received.
- A fiber optic plate coupled to the scintillator passes the visible light to the CMOS (complementary metal-oxide semiconductor) sensor while blocking x-ray energy.
- The visible light is captured by the circuitry of the CMOS sensor, converting visible light into an electrical signal proportional to the visible light received.
- An analog to digital converter processes the signal prior to transfer to the host computer via the USB cable.

The primary difference between the two devices is that the CMOS in the SuniIQ incorporates an improved pixel design that increases the surface area of the transistors, which supports increasing the pixel voltage resetting value from 2.9 V to 3.5 V. This allows more x-ray converted charge to be integrated into each pixel, resulting in a 30% increase in x-ray exposure range over the SuniRay II. The SuniIQ also incorporates an improved system for image correction compared to the SuniRayII, with a 2D fault correction map that is derived from characterization of each pixel. Finally, the outer jacket of the sensor incorporates a green colorant; the outer jacket of the predicate SuniRayII has a black colorant.

The software components of the SuniIQ (SuniIQ USB software version 2.0 and SuniIQ Driver SDK version 10.0.1.2) provide the features of the software components of the predicate device, and add the functionality of a new sensor type and an optional 3x3 optional filter algorithm. As with the predicate device, the software does not incorporate a Graphical User Interface (GUI) or other user-controlled image processing/viewing functionality.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The SuniIQ Digital Radiography System reduces x-ray exposure by producing real time digital intra-oral images. The System accomplishes this by replacing X-ray film with a reusable electronic sensor that captures the X-ray photons and converts them to an electronic signal which, in turn, is captured in a computer for viewing, manipulating, storing, and output.



There are two models of the SuniIQ. The only difference between the two models is the size of the sensor. The sensor sizes correspond to #1 and #2 dental film.

Model	Sensor Dimensions (mm)	Active Area (mm)
400-1321 – Size 1	39.5 x 26	31.1 x 20.2
400-1322 – Size 2	43.5 x 31.5	35.2 x 26.2

The SuniIQ Sensor (1) incorporates a CMOS detector for capture and imaging of x-ray photons. The sensor is encapsulated into a plastic housing and is connected via a cable to the SuniIQ USB interface electronics module (2). The USB-interface has two LEDs that indicate USB power (4) and interface activity (5).

The USB Interface is connected to a USB cable using a type "mini-B" USB connector (3). The other end of this cable terminates in a USB plug (6) for connection to a USB port on the host computer.

The System also includes software drivers that control the USB interface module and a Graphical User Interface (GUI) which allows the user access to the data and to control functions of the System.

The SuniIQ is intended to be used with dedicated dental x-ray Imaging software to provide the dental professional user the benefits of "real time" imaging system. The software manufactured by Apteryx (K983111) is such dedicated dental software for dental x-ray imaging.

The System sensors are available in two formats. The #2 size (400-1322) is a larger sensor typical of the European format and the # 1 size (400-1321) 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 in a plastic enclosure with a three-foot cable that is connected to the USB interface electronics module.

The USB interface electronics module plugs into a computer USB port via a supplied USB cable. The USB interface electronics module contains the support and control circuitry for the sensor and allows for data communications with the computer. The USB interface electronics module 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 interface electronics module 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.

INDICATIONS FOR USE:

The SuniIQ 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.

TECHNICAL CHARACTERISTICS:

The SuniIQ Digital Radiography System replaces X-ray film with a reusable electronic sensor that captures the X-ray photons and converts them to an electronic signal which in turn is captured in a computer for viewing, manipulating, storing, and output. The SuniIQ is intended to be used with dedicated dental x-ray imaging software to provide the dental professional user the benefits of "real time" imaging system.

The SuniIQ Sensor incorporates a CMOS detector for capture and imaging of x-ray photons. The sensor is encapsulated into a plastic housing and is connected via a cable to the SuniIQ USB interface electronics module.

The USB-interface provides two LEDs to indicate USB power and interface activity. The USB Interface is connected with a provided USB cable to a USB port on the host computer. The USB interface electronics module contains the support and control circuitry for the sensor and allows for data communications with the computer. The USB interface electronics module 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 interface electronics module communicates with the computer under control of a specific device driver that is active with the GUI.

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

PERFORMANCE STANDARDS:

No applicable performance standards have been issued under 514 of the Food, Drug and Cosmetic Act for a System, X-Ray, Extraoral Source, Digital §872.1800.

SUMMARY OF NONCLINICAL TESTING:

Testing was performed to assure the performance and safety of the SuniIQ System.

Bench Testing
Bench testing confirmed that the performance of the SuniIQ System meets all functional requirements. This testing included, where relevant, direct comparison to the performance of the predicate SuniRay II System.

SuniIQ Bench Test Summary

Tested Function	Result
Relative error	Pass
X-Ray Saturation	Pass
Image size	Pass
Image orientation	Pass
Set up time, USB current and clock pattern	Pass
Dose loss and focus to detector distance (FDD)	Pass
Saturation Comparison	Pass
Printed Circuit Board (PCB)	Pass
Software Development Kit (SDK)	Pass
Time to ready for exposure state	Pass
Test Pattern Images	Pass
Dental Phantom Images	Pass
Other Operating systems	Pass

Software V&V
Software verification & validation testing was conducted in accordance with IEC 62304:2006: *Medical device software -- Software Life Cycle Processes* and with FDA guidances for software development and testing (*Guidance for the Content of Premarket Submission for Medical Device Containing Software*, FDA-CDRH-CBER, Rockville, MD, 05/2005; *Guidance for Off-the-Shelf Software Use in Medical Devices*, FDA- CDRH, Rockville, MD, 06/1997; and *General Principles of Software Validation; Final Guidance for Industry and FDA Staff*, FDA-CDRH, Rockville, MD, 01/2002). All features provided for the SuniIQ System have been verified to operate as specified. The software systems were treated as entirely new systems in respect to specification and verification to adjust the documentation and verification requirements to the current state of technology. All test passing criteria for the Software V&V were met. Both software systems were verified entirely to establish a new baseline and regression testing was therefore not indicated.

Biocompatibility
The materials of the device have been evaluated, tested, and determined to meet requirements under ISO 10993-1:2009 Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process, and the FDA draft guidance document Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (April 23, 2013).

Disinfection
The recommended cleaning method (intermediate level of disinfection) has been evaluated and confirmed. Testing was performed under Good Laboratory Practices regulations (21CFR 58 Good Laboratory Practice for Nonclinical Laboratory Studies).

Electromagnetic Compatibility and Electrical Safety
The System meets the requirements of IEC 60601-1:2005 and ANSI/AAMI ES60601-1:2005 for safety, IEC 60601-1-2:2007 for electromagnetic compatibility.

All features provided for the SuniIQ System have been verified to operate as specified. Testing confirms that the SuniIQ System is as safe, as effective, and performs as well as or better than the predicate device.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The SuniIQ Digital Radiography System is substantially equivalent to the listed predicate device with respect to indications for use (intended use) and technical characteristics. The information and data provided in this 510(k) submission identifies no new safety or effectiveness issues.

ELEMENT	SUNIIQ	SUNRAY II K070219
Indications for Use	"… to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed and manipulated for diagnostic use by dentists."	"… to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed and manipulated for diagnostic use by dentists."
Design Features		
Indirect converting CMOS detector	✓	✓
USB power supply	✓	✓
USB data interface	✓	✓
Active imaging area: Size 1: 31.1 x 20.2mm² Size 2. 35.2 x 26.2 mm²	✓	✓
33 µm pixel pitch	✓	✓
4096:1 dynamic range	✓	✓
Materials (potential patient contact) Ultem HU1010 sensor enclosure Polyurethane cable jacket	✓	✓
Detector to USB A cable length	✓	✓

ELEMENT	SUNIQ	SUNRAY II K070219
= 70cm + length of USB cable		
Detector to USB B cable length = 70cm + length of USB cable	✓	✓
Principles of Operation		
Indirect converting CMOS (complementary metal-oxide semiconductor) detector	✓	✓
• Cesium-Iodide (CsI) scintillator: emits visible light in proportion to the x-ray energy received	✓	✓
• Fiber optic plate; coupled to scintillator, transmits light to CMOS while blocking x-rays	✓	✓
• CMOS captures visible light into a matrix of photodiodes and other transistors, each forming a pixel of the resulting image.	✓	✓
• Photodiodes are n-well over p-type substrate	✓	✓
• Each pixel consists of 3 NMOS transistors and a photodiode.	✓	✓
• Pixel voltage resetting value	3.5V	2.9V

The identified technological differences between the subject and predicate devices were assessed through bench performance testing data and software V&V testing to demonstrate that they are substantially equivalent.