Remedi Co. Ltd.
% W. Lee Strong
Quality Systems Manager
510K FDA, Inc.
100 E Granada Blvd, Suite 219
ORMOND BEACH FL 32176

February 28, 2020

Re: K200284
Trade/Device Name: R-Sensor
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: January 23, 2020
Received: February 5, 2020

Dear W. Lee Strong:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K200284

Device Name
R-Sensor

Indications for Use *(Describe)*
R-Sensor is used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510k FDA Consulting
Medical Device Clearance

100 East Granada Blvd., Suite 219 Ormond Beach, FL 32176 386-506-8711

510 (k) Summary

Submitter/Applicant

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Date Prepared: January 31, 2020

Preparer/Consultant

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Ormond Beach, FL 32176

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Primary Contact: Lee Strong, Quality Systems Manager, lee@510kfda.com
Secondary Contacts: Claude Berthoin, President (claude@510kfda.com).

Device Classification

Trade Name:	R-Sensor
Common Name:	Intraoral Digital X-Ray Sensor
Regulation Number:	21 CFR 872.1800
Classification Name:	Extraoral Source X-Ray System
Product Code:	MUH
Submission Type:	510(k)
Regulatory Class:	2
Medical Specialty:	Dental

FDA Guidance

The following guidance documents were utilized in the development of this device:

1. *Guidance for the Submission of 510(k)'s for Solid State Imaging Devices*
2. *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*
3. *Postmarket Management of Cybersecurity in Medical Devices*
4. *Pediatric Information for X-ray Imaging Device Premarket Notifications*
5. *Guidance for Industry and FDA on Alternative to Certain Prescription Device Labeling Requirements*
6. *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices*

Predicate Device

The following predicate is a legally marketed, post-amendment device:

510(k) Number: K151926
Clearance Date: December 14, 2015
Actual Trade Name: QuickRay HD
Regulation & PC: 872.1800; MUH

K151926 is identical to the subject device.

Device Description

The subject R-Sensor is an intraoral digital x-ray system comprised of two components: (1) an intraoral detector which connects to a PC via a USB port; and (2) an Image Management Software package.

The subject devices comes in two sizes: Size 1 is 600mm² and Size 2 is 884mm².

R-Sensor, Size 1 is also known as factory code S11684-12; R-Sensor, Size 2 is also known as factory code S116845-12.

Before Remedi sells this device, our technicians discuss the hardware and software that the dentist has, to make sure that their systems are compatible with the R-Sensor. Remedi offers technical support for this device to ensure proper operation and to answer any questions regarding the function of the device. A means to contact Remedi is provided to all end users and in our user manual.

The type of x-ray systems that integrate with the R-Sensor are wall-mounted x-ray generators (both AC and DC) with a tube current between 1 and 15 mA inclusive, and with a tube voltage between 50 and 100 kV inclusive, with in-built controls to set exposure parameters. Generators allow variable mA/kV to be selected, all will control the exposure time.

This device and software cannot act as an x-ray generator controller. All control of x-ray generation is done by controls built into the generator itself. **There is no connection between the subject device and the x-ray generator. The subject device does not control the generator, it is a receiver.**

X-ray Vision, software by Apteryx (K983111) cleared on November 16, 1998, is supported on Windows XP, Vista, 7, 8, 8.1 and 10. Absolute minimum requirements for PC hardware for the sensor and software combination would be a Pentium 4 or better processor. At least 1 GB of RAM, 200MB of hard drive space for the software, plus additional space for the user database (recommended 40GB minimum), a USB 2.0 or 3.0 and a 100MB wired Ethernet connection is needed if networked.

The Xray Vision software by Apteryx is a Windows based image management database/software primarily used by dentists to acquire, enhance, store, communicate, print, recall and display digital images.

The firmware in the R-Sensor has already been cleared. The subject device is the exact same device as the QuickRay HD sensor, K151926. The subject device is identical in firmware/hardware from Hamamatsu, and the software is identical from Apteryx. Hamamatsu is the main subcontractor of this device for Remedi International, Inc.

The QuickRay HD device also has 2 sizes like our subject device. The subject device and the QuickRay HD device are identical in all aspects of the device. They will have different names only for marketing purposes and that does not change the safety and effectiveness of the subject device.

The latest publication of CR Clinicians the November newsletter reports that 70% of all the practices use dental sensors and only 16% use film. This newsletter may be reviewed in section 21 _Other.

Indications for Use

R-Sensor is used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.

Intended Use

Radiographic examination to assist with diagnosis of diseases of the teeth, jaw, and oral structure.

The R-Sensor dental sensor is intended to replace film and to capture an intraoral x-ray image, when exposed to X-rays, for dental diagnostic purposes.

Comparison of Technological Characteristics with Predicate

The subject R-Sensor and predicate QuickRay HD are identical dental devices.

Both are comprised of the following two components…

- Intraoral Detector System… The subject device and predicate device include an intraoral detector, flexible cord, and direct USB 2.0 plug, as described in subject R-Sensor and predicate QuickRay HD marketing literature in this petition.

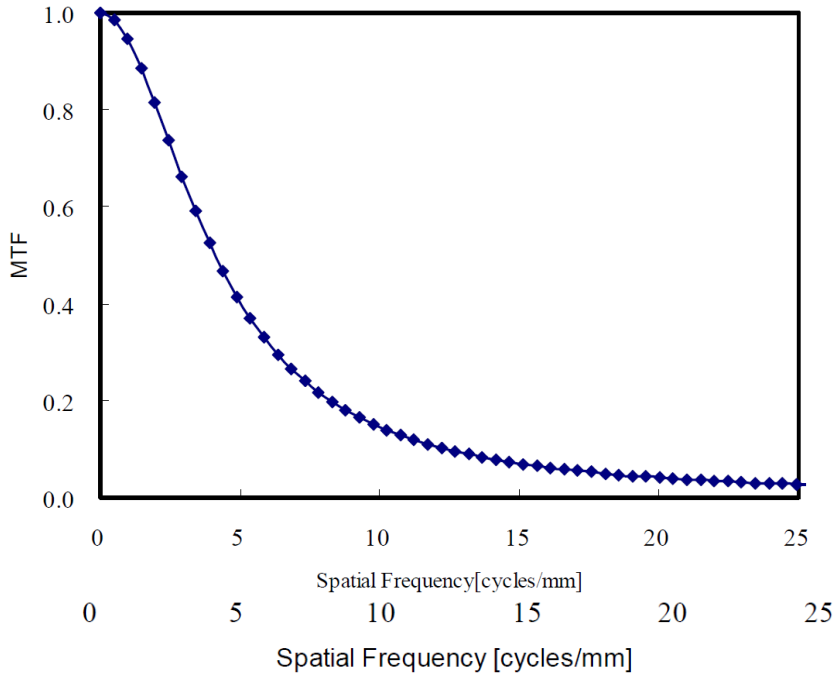
- Imaging Software… Both the subject and predicate use a third party software called Xray Vision which is manufactured by Apteryx in Akron, Ohio (K983111) cleared November 16, 1998.

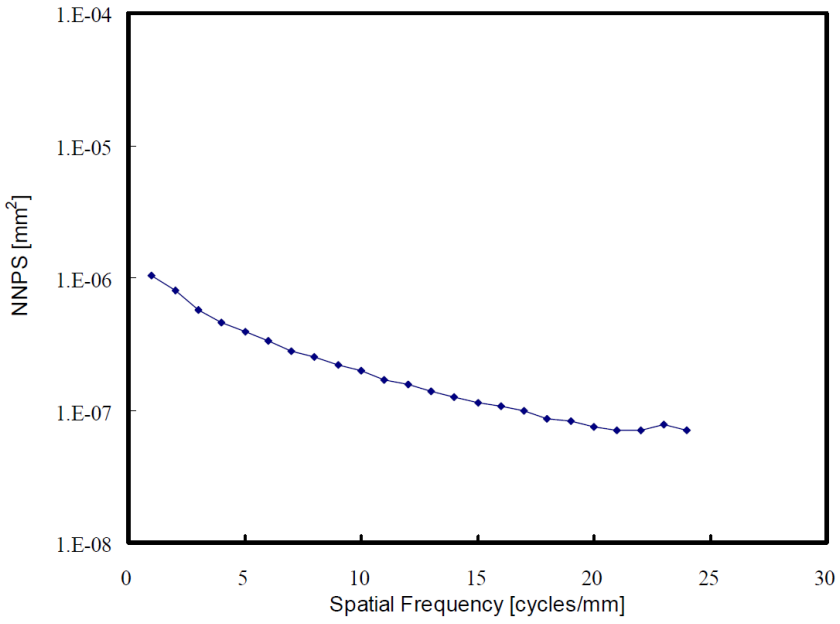
Comparison Table	R-Sensor K200284	QuickRay HD	Differences
510(k)	Not assigned yet	K151926	NA
Applicant/Assembler/ Repackager/Relabeler	Remedi Co, Ltd. (Ormond Beach, FL)	Denterprise Intl, Inc. (Ormond Beach, FL)	NA
Manufacturer—Imaging SW Component	Apteryx (Akron, OH)	Apteryx (Akron, OH)	Same
Classification & Product Code	872.1800; MUH	872.1800; MUH	Same
Common name	Intraoral Digital X-Ray Sensor	Intraoral Digital X-Ray Sensor	Same
Intended use	Radiographic examination to assist with diagnosis of diseases of the teeth, jaw, and oral structure.	Radiographic examination to assist with diagnosis of diseases of the teeth, jaw, and oral structure.	Same
Principles of operation	X-ray (radiation) => scintillator (convert to light) => fiber optic (filtering) => CMOS (convert to digital) => electronics => PC (capture & display image)	X-ray (radiation) => scintillator (convert to light) => fiber optic (filtering) => CMOS (convert to digital) => electronics => PC (capture & display image)	Same
Software—Firmware	Firmware combined on sensor electronic board	Firmware combined on sensor electronic board	Same
Software—Image Management	Xray Vision (OTS package from Apteryx, USA)	Xray Vision (OTS package from Apteryx, USA)	Same
Sensor technology	CMOS chip + optical fiber plate + CSi scintillator	CMOS chip + optical fiber plate + CSi scintillator	Same
Matrix dimensions (mm2)	Active area: 600mm² (Size 1) 884mm² (Size 2)	Active area: 600mm² (Size 1) 884mm² (Size 2)	Same

Comparison Table	R-Sensor K200284	QuickRay HD	Differences
Matrix dimensions (pixels)	1000 lines X 1500 columns (Size 1); 1300 X 1700 (Size 2).	1000 lines X 1500 columns (Size 1); 1300 X 1700 (Size 2).	Same
Lifespan CMOS	Min. 100,000 cycles	Min. 100,000 cycles	Same
Resolution	Real ≥ 20pl/mm	Real ≥ 20pl/mm	Same
Pixel size	20 X 20µm	20 X 20µm	Same
Grey levels	14 bits	14 bits	Same
Sensor board	All control electronics directly integrated on CMOS sensor chip	All control electronics directly integrated on CMOS sensor chip	Same
Sensor shell	Specific shape design; material is ABS and the flammability is HB if YK-94 (UL File No. 49895)	Specific shape design; material is ABS and the flammability is HB if YK-94 (UL File No. 49895)	Same
Cable material and design	Cable consists of PVC, ETFE, copper, plug connector and sensor connector, diameter ϕ3.7 ±0.3 and cable length 2 meters.	Cable consists of PVC, ETFE, copper, plug connector and sensor connector, diameter ϕ3.7 ±0.3 and cable length 2 meters.	Same
Connection to imaging practice PC	USB 2.0 High-Speed	USB 2.0 High-Speed	Same
Operating temperature	0°C to 35°C	0°C to 35°C	Same
Sensor input voltage and current	5V (via USB connection); 0.15A Max	5V (via USB connection); 0.15A Max	Same
Standards of conformity	IEC 60601-1 (Electrical); IEC 60601-1-2 (EMC) 62220-1 (Performance) 60529 (IP Code)	IEC 60601-1 (Electrical); IEC 60601-1-2 (EMC) 62220-1 (Performance) 60529 (IP Code)	Same

Input Calculation software*1 Output

$$DQE = \frac{MTF^2}{\Phi \cdot NNPS}$$





Performance Data

Clinical images were examined by Dr. Parham, a qualified practitioner in Ormond Beach, FL and found to be diagnostically relevant and reliable.

Clinical images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the predicate device but they provide further evidence in addition to bench testing data to show that the complete system works as intended.

Biocompatibility

Biocompatible testing for the subject is not warranted because there are no direct or indirect patient-contacting components in the subject device. It is covered with a single-use protective barrier prior to each use just like the QuickRay HD predicate.

Electrical Safety and EMC

EMC and electrical safety testing data reports for the subject device are provided in this petition.

- The R-Sensor conforms to electrical and safety standard IEC 60601-1 (Medical Electrical Equipment, Part I: General requirements for basic safety and essential performance).

- The R-Sensor conforms to electrical and safety standard IEC 60601-1-2 (Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential 3271performance – collateral standard: Electromagnetic compatibility).

Software Verification and Validation Testing

R-Sensor electronics contains firmware along with a driver both provided by Hamamatsu. Additionally, R-Sensor uses image management software provided by Apteryx Company; therefore, only firmware and driver documentation for the subject device are included in this petition.

Bench Testing

Bench tests were performed in conformance with IEC 62220-1 (Medical Electrical Equipment – Characteristics of Digital X-ray Imaging Devices—Part 1: Determination of the Detective Quantum Efficiency and IEC 60529 (Degrees of Protection Provided by Enclosures—IP Codes).

Conclusions

The subject and the predicate device have the same intended use, same design, and the same technological features. R-Sensor and QuickRay HD share the same principles of operation, sensor technology, use the same USB connection to PC and use the same imaging firmware. The conclusion is that the subject device is as safe and effective as the predicate.

The sensors will only have different brand names for marketing purposes. Therefore, R-Sensor warrants a finding of substantial equivalence to the QuickRay HD and thus clearance for premarket activities in the United States.