September 15, 2021

Rolence Enterprise Inc.
% Ben Chang
QA Associate Manager
18-3 Lane 231 Pu Chung Rd., Chungli
Taoyuan, 32083
TAIWAN

Re: K202369
Trade/Device Name: RXS 1000
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: July 14, 2021
Received: August 6, 2021

Dear Ben Chang:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202369

Device Name
RXS 1000

Indications for Use *(Describe)*
The RXS 1000 is an Intraoral Digital X-ray Sensor and is intended to be used by dentists and dental technicians diagnostic diseases of the teeth, jaw and oral structures. Its use is intended for adult subjects.

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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Submitter's Information:

Firm Name: Rolence Enterprise Inc.
Address: 18-3 Lane 231 Pu Chung Rd., Chungli, Taoyuan, Taiwan
Phone: +886-3-4631999
FAX: +886-3-4631997

Contact Person:

Contact: Ben Chang
Position: QA Associate Manager
E-mail: ben@rolence.com.tw
Phone: +886-3-4631999
FAX: +886-3-4631997

Date of Summary Preparation: 2020/7/28

Device Information:

510(k) Number: K202369
Trade Name (Model Name): RXS 1000
Common Name: Intraoral Digital X-ray Sensor
Classification Name: System, X-Ray, Extraoral Source, Digital
Classification: Class II per 21 CFR 872.1800
Product Code: MUH
Classification Panel: Dental

Predicate Device Information:

510(k) Number: K163282
Trade Name: Apex Dental Sensors Size #1
Common Name: Intraoral Digital X-ray Sensor
Classification Name: System, X-Ray, Extraoral Source, Digital
Classification: Class II per 21 CFR 872.1800
Product Code: MUH
Classification Panel: Dental

Device Description:

The RXS1000 is intended to acquire real-time, clinical digital intraoral X-ray images using a solidstate imaging sensor. This system consists of the CMOS sensor and software for image display. This system senses the onset of the X-ray exposure and automatically acquires and save the image data to a PC(software).

Indication for Use:

The RXS 1000 is intended to be used by dentists and dental technicians diagnostic diseases of the teeth, jaw and oral structures. Its use is intended for adult subjects.

Technological Characteristics:

Parameter	Subject Device	Predicate Device	Equivalent or Difference
Model Name	RXS 1000	Apex Dental Sensors Size #1	N/A
K Number	K202369	K163282	N/A
Manufacturer	Rolence Enterprise Inc.	Masterlink LLC	N/A
Classification Name	System, X-Ray, Extraoral Source, Digital	System, X-Ray, Extraoral Source, Digital	Equivalent
Classification	Class II 21 CFR 872.1800	Class II 21 CFR 872.1800	Equivalent
Product Code	MUH	MUH	Equivalent
Classification Panel	Dental	Dental	Equivalent
Indications for use	The RXS 1000 is intended to be used by dentists and dental technicians diagnostic diseases of the teeth, jaw and oral structures. Its use is intended for adult subjects.	The Apex Dental Sensors is intended to be used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.	Equivalent
Sensor type	CMOS	CMOS	Equivalent
Scintillator Material	CsI	CsI	Equivalent
Sensor dimension	42 x 26.2 x 6.7 mm	39 x 25 x 5.3 mm	RXS 1000 is larger than predicate device, but patient isn't feel uncomfortable when use.
Image area	30 x 20 mm	30 x 20 mm	Equivalent
Pixel size	20 x 20 μm	20 x 20 μm	Equivalent
Resolution	1500 x 1000 pixels	1500 x 1000 pixels	Equivalent
DQE	More than 20% at 3.5 lp/mm	More than 20% at 3.5 lp/mm	Equivalent

MTF	More than 40% at 5 lp/mm	More than 40% at 5 lp/mm	Equivalent
Cable length	3 m	2 m	For our research, user prefer 3m length cable.
USB interface	USB 3.0	USB 2.0	USB 3.0 is not only higher transfer data speed, but also can backwards compatibility USB 2.0 interface.
Sensor Input Voltage	DC 5V	DC 5V	Equivalent

Summary of Testing:

RXS 1000 applied IEC standards for IEC 60601-1 and IEC 60601-1-2. Risk management was according to ISO 14971. Performance testing, software documentation conducted were according to FDA guidance.

Conclusion:

Except the dimension and USB cable length, RXS 1000's specification is equivalent to predicate device.