September 13, 2023

Genoray Co., Ltd.
% Ms. Kaitlynn Min
Business Development
GENORAY America Inc.
1220 N Simon Circle, Unit B
ANAHEIM CA 92806

Re: K232158
Trade/Device Name: GenX-CR
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: July 19, 2023
Received: July 20, 2023

Dear Ms. Min:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

GenX-CR is a digital radiographic scanner for dental diagnostics intended for use by dentists and other qualified professionals.

This device is used to create and display digital images by scanning intraoral X-ray images stored in an Image Plate (or Phosphore Storage Plate).

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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510(k) Summary - K232158

This 510(k) summary information is prepared in accordance with 21 CFR 807.92

1. Date of Summary Preparation [21 CFR 807.92(a) (1)]

: Jul. 14, 2023

2. Administrative Information [21 CFR 807.92(a) (1)]

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3. Device Information [21 CFR 807.92(a) (2)]

Trade / Device Name	GenX-CR
Regulation Name	Extraoral source X-ray system
Classification Regulation	21 CFR 872.1800
Class of Device	Class II
Panel	Radiology
Product Code	MUH

4. Predicate Device Information [21 CFR 807.92(a) (3)]

*** Predicate Device**

Name of Device	CRUXCAN(CRX-1000)
Manufacturer	CRUXELL Corp.
Regulation Name	Extraoral source X-ray system
Classification Regulation	21 CFR 872.1800
Class of Device	Class II
Panel	Radiology
Product Code	MUH

5. Description of the Device [21 CFR 807.92(a) (4)]

GenX-CR scans a reusable phosphor storage plate (hereinafter referred to as “PSP”) instead of an analog film to acquire high-quality digital radiographic images, digitally processes them, and displays images on the equipment's touch display screen and computer screen. It’s a scanner.
*PSP is also known as IP (Image Plate)

After scanning the PSP, the image is saved in the device’s internal memory, the scanned image can be checked in advance through the touch display, and the image stored in the PSP can be deleted and the PSP can be ejected. Scanned images can be directly transmitted to a computer or network via an Ethernet cable and are used in PortView, a dental diagnostic software package, and other diagnostic software.

GenX-CR is composed of mainly consists of PSP Scanner, PSP tray, power adapter and cable, Ethernet cable, PSP transfer box, PSP, PSP Protective Cover, Hygenic Bag, Dental PSP scanner control system software (Version: V2.2)

GenX-CR contains firmware that is part of the system. And we hereby certify that the level of concern for this software(PortView) and firmware(GenX-OP) is of Moderate level of concern. And It has not been cleared with other predicate devices but is the initial used in GenX-CR

Its compact design allows installation in space-constrained locations and minimizeds operating costs by using a low-cost, reusable PSP.

6. Indications for use [21 CFR 807.92(a) (5)]

GenX-CR is a digital radiographic scanner for dental diagnostics intended for use by dentists and other qualified professionals.
This device is used to create and display digital images by scanning intraoral X-ray images stored in an Image Plate (or Phosphor Storage Plate).

7. Substantial equivalence chart [21 CFR 807.92(a) (6)]

	Proposed device	Predicate device	SE Note
	GenX-CR	**CRUXCAN(CRX-1000)**	
Manufacturer	GENORAY Co., Ltd	CRUXELL Corp.	-
510(k) No.	K232158	K183637	-
Regulation Name	Extraoral source X-ray system	Extraoral source X-ray system	-
Classification name	System, X-ray, Extraoral Source, Digital	System, X-ray, Extraoral Source, Digital	
Common Name	Dental PSP Scanner	Dental PSP Scanner	
Product Code	MUH	MUH	-
Regulation Number	872.1800	872.1800	-
Class	Class II	Class II	-
Product illustraion	 		-
Indications for use	GenX-CR is a digital radiographic scanner for dental diagnostics intended for use by	The CRUXCAN (CRX-1000) is indicated for capturing, digitization and processing of	Same

	dentists and other qualified professionals. This device is used to create and display digital images by scanning intraoral X-ray images stored in an Image Plate (or Phosphore Storage Plate).	intra-oral x-ray images stored in imaging plate recording media.	
Image File Format	TIFF / Raw Format	TIFF / Raw Format	Same
Power Supply	50/60 Hz, 100-240V~	50/60 Hz, 100-240V~	Same
X-ray Absorber	Imaging Plate	Imaging Plate	Same
Image plate Size	Size 0 : 22 x 31mm Size 1 : 24 x 40 mm Size 2 : 31 x 41mm Size 3 : 27 x 54 mm	Size 0 : 22 x 31mm Size 1 : 24 x 40 mm Size 2 : 31 x 41mm Size 3 : 27 x 54 mm	Same
Image Pixel Size	25 um (High Resolution) 50 um (Standard Resolution)	25 um 50 um	Same
Gray Scale level	16 bit	8 bit / 16 bit	Same
Resolution	12 lp/mm @ 25um	14.0 lp/mm @ 25um	Similar
Imaging Plate Performance **- DQE** **- MTF**	DQE at 10% efficiency: 2.8 lp/mm MTF at 3lp/mm: 35%	DQE at 10% efficiency: 2.8 lp/mm MTF at 3lp/mm: 35%	Same
Laser safety classification	Class 1 laser product EN60825-1:2014	Class 1 laser product EN60825-1:2014	Same

8. Safety, EMC and Performance data comparison to Predicate [21 CFR 807.92(b)]

GenX-CR has been successfully completed verification and validation testing per GENORAY quality system and engineering bench testing in support of successfully completed verification and validation testing per GENORAY quality system and this submission.
The system has been tested and is compliant with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-2-65, IEC 62366.

And Software was validated according to the FDA Guidance “Guidance for the Content of Premarket Submissions for Software Contained in Medical devices", FDA Guidance "Guidance for the content of premarket submissions for management of cyber security". Results demonstrated that all executed verification tests were passed.

Non-clinical validation testing has been performed to validate that GenX-CR conforms to the intended use, claims, user needs, effectiveness of safety measures, and instructions for use. Clinical testing was not necessary for the subject device, to demonstrate substantial equivalence.

As a result, all test results were satisfactory, and the result of bench tests indicates that the new device is as safe and effective as the predicate device.

9. Conclusion

In reference to the comparison information provided in the substantial equivalence chart, and the most of functions and electronic features are similar to the predicate device. We believe that the GenX-CR is safe and effective as a predicate device and has no new indication for use. Therefore, GenX-CR is substantially equivalent to a predicate device.