December 8, 2023

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

Re: K232085
Trade/Device Name: DVAS (DVAS-M, DVAS-W)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: EHD
Dated: June 20, 2023
Received: November 3, 2023

Dear Kaitlynn 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Radiologic 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232085

Device Name

DVAS (DVAS-M, DVAS-W)

Indications for Use *(Describe)*

DVAS is an extra-oral source x-ray system to be used by trained dentists and dental technicians as an extra-oral x-ray source for producing diagnostic dental radiographic examination and diagnosis of teeth, jaw, and other oral structures using intra-oral image receptors. It is intended for both adult and pediatric 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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Exhibit 5 **510(k) Summary** K232085

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)]**

   : Jun. 20, 2023

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

510(k) Submitter	GENORAY Co.,Ltd Address: 512, 560, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-Do, Korea Telephone No.: +82-31-5178-5500 Fax: +82-31-5178-5599 Contact Person: Inyoung Kim (iykim@genoray.com)
Official Correspondent	GENORAY America Inc. Address: 1220N Simon Circle, Anaheim, B, CA 92806 USA Telephone No.: +1-855-436-6729 Fax: +1-714-786-8919 Contact Person: Kaitlynn Min (kaitlynn@genorayamerica.com)

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

Trade / Device Name	DVAS (DVAS-M, DVAS-W)
Common or Usual Name	Dental X-ray system
Classification Name	Extraoral source X-ray system
Classification Regulation	21 CFR 872.1800
Class of Device	Class II
Panel	Radiology
Product Code	EHD

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

*** Predicate Device**

Name of Device	RIX 70 DC (K182206)
Manufacturer	Trident s.r.l., Italy
Common or Usual Name	Extraoral source X-ray system
Classification Name	Unit, X-ray, Extraoral with Timer
Classification Regulation	21 CFR 872.1800
Class of Device	Class II
Panel	Radiology
Product Code	EHD

*** Reference Device**

Name of Device	PORT-X IV (K172810)
Manufacturer	GENORAY Co., Ltd
Common or Usual Name	Extraoral source X-ray system
Classification Name	Unit, X-ray, Extraoral with Timer
Classification Regulation	21 CFR 872.1800
Class of Device	Class II
Panel	Radiology
Product Code	EHD

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

DVAS, the extra-oral source x-ray system for dentistry is the standard X-ray equipment used to acquire intraoral images of patients during dental diagnosis such as dental caries, periodontal diseases, dental root fracture, and other oral and dental pathologies.
DVAS is used to provide anatomic X-ray images of a patient at hospitals or dental clinics using a cone for X-ray exposure.

The doctor or dentist can check the acquired X-ray images with chemical films or a PC monitor.

No.	Item	Specification
1	Pixel Size	≤ 40 μm
2	Active area size	≥ 19 mm x 26 mm(Size 0)
3	Resolution	≥ 10(lm/mm)
4	Digital sensor plate thickness	≤ 19 μm * 19 μm
5	Interface	USB

DVAS can be used Digital I/O Sensor, Image plate (CR), Film as a Image receptor. The image receptors are not part of this submission. And the minimum integration requirements for intra-oral detectors when used with this device are:

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

DVAS is an extra-oral source x-ray system to be used by trained dentists and dental technicians as an extra-oral x-ray source for producing diagnostic dental radiographic examination and diagnosis of teeth, jaw, and other oral structures using intra-oral image receptors. It is intended for both adult and pediatric subjects.

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

	Proposed device		Predicate device		Reference device	SE Note
	DVAS-M	**DVAS-W**	**RIX 70 DC**		**PORT-X IV**	
Manufacturer	GENORAY Co., Ltd		Trident s.r.l., Italy		GENORAY Co., Ltd	-
510(k) No.	K232085		K182206		K172810	-
Classification Name	Extraoral source x-ray system		Extraoral source x-ray system		Extraoral source x-ray system	-
Product Code	EHD		EHD		EHD	-
Regulation Number	872.1800		872.1800		872.1800	-
Class	Class II		Class II		Class II	-
Product illustraion						-
Indication	DVAS is an extra-oral source x-ray		RiX70 DC X-ray Unit is designed for use in		PORT-X IV is a	Same

s for use	system to be used by trained dentists and dental technicians as an extra oral x-ray source for producing diagnostic dental radiographic examination and diagnosis of teeth, jaw, and other oral structures using intra oral image receptors. It is intended for both adult and pediatric subjects.		dental surgery to make endo-oral x-rays for diagnostic purposes. This equipment can be used to produce traditional x-rays developed using chemicals or, alternatively, it can be used with digital x-ray sensors.		portable X-ray system to be used by trained dentists and dental technicians as a mobile, extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is intended for both adult and pediatric subjects.	
Patient type	Adult - Child		Adult - Child		Adult - Child	Same
Mechanical						
Mechanical configuration	Floor-mounted type	Wall-mounted type	Floor-mounted type	Wall-mounted type	Mobile type	Same
Minimum source to skin distance	200mm		200mm		-	Same
X-ray field Size (default)	60mm round		60mm round		60mm round	Same
Duty	1:50		1:30		1:30 or more	Similar

Cycle				
Target material	Tungsten	Tungsten	Tungsten	Same
Target angle	12.5°	16°	12.5°	Similar
Electrical				
Electrical power voltage	AC 100-240V	AC 100-240V	AC 100-240V	Same
Focal spot	0.4mm	0.4mm	0.4mm	Same
Exposure time	0.05 ~ 1.6s	0.02~2.0s	0.05 ~ 1.6s	Similar
Tube current	2.0mA fixed	7mA fixed	2mA fixed	Similar
Tube voltage	70kV fixed	60, 65, 70kV	70kV fixed	Similar
Applied standard	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-2-65 21 CFR 1020.30 21 CFR 1020.31	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-2-65 21 CFR 1020.30 21 CFR 1020.31	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-2-65 21 CFR 1020.30 21 CFR 1020.31	Same

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

DVAS have been successfully compeleted verification and validation testing per GENORAY quality system as well 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. Also, DVAS complies with all applicable 21 CFR performance standards (21 CFR 1020.30, 21 CFR 1020.31)

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.

DVAS can be used not only in adults but also In the pediatric population, and therefore the system has reflected pediatric information in the labeling according to the FDA Guidance ‘’Pediatric Information for X-ray Imaging Device Premarket Notifications,” dated November 28, 2017”

Non-clinical validation testing has been performed to validate that DVAS conform to the intended use, claims, user needs, effectiveness of safety measures and instructions for use.

As a results, 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 with the predicate device. We believe that the DVAS are safe and effective as predicate device, and have no new indication for use. Therefore, DVAS are substantially equivalent to predicate device.