July 20, 2023

Genoray Co., Ltd.
% Kaitlynn Min
Business Development
Genoray America Inc.
147 E. Bristol Lane
ORANGE, CA 92865

Re: K230787
Trade/Device Name: Oscar 15 & Oscar 15i
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: May 22, 2023
Received: July 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 (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)*
K230787

Device Name
OSCAR 15 & OSCAR 15i

Indications for Use *(Describe)*
OSCAR 15 & OSCAR 15i are a mobile fluoroscopy system designed to provide fluoroscopic and spot film images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac and critical care. The system may be used for other imaging applications at the physician's discretion. OSCAR 15 and OSCAR 15i are indicated only for adult patients.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Exhibit 5 **510(k) Summary** K230787

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)]**

: Mar. 08, 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.: +82-31-5178-5771 Fax: +82-31-5178-5599 Contact Person: JiYeon Choi(jychoi@genoray.com)
Official Correspondent	GENORAY America Inc. Address: 147 E. Bristol Lane, Orange, CA 92865 USA Telephone No.: +1-855-436-6729 Fax: +1-714-786-8919 Contact Person: Kaitlynn Min (kaitlynn@genorayamerica.com)

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

Trade / Device Name:	OSCAR 15 & OSACR 15i
Common or Usual Name:	Fluoroscopic X-ray System
Classification Name:	Interventional Fluoroscopic X-ray System
Classification Regulation:	21 CFR 892.1650
Class of Device:	Class II
Panel:	Radiology
Product Code:	OWB / Interventional Fluoroscopic X-Ray System
Subsequence product code:	JAA / System, X-Ray, Fluoroscopic, Image-Intensified

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

Manufacturer:	GENORAY Co., Ltd
Name of Device:	OSCAR 15 (K172180)
Common or Usual Name:	Fluoroscopic X-ray System
Classification Name:	Interventional Fluoroscopic X-ray System
Classification Regulation:	21 CFR 892.1650
Class of Device:	Class II
Panel:	Radiology
Product Code:	OWB / Interventional Fluoroscopic X-Ray System

Subsequence product code: JAA / System, X-Ray, Fluoroscopic, Image-Intensified

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

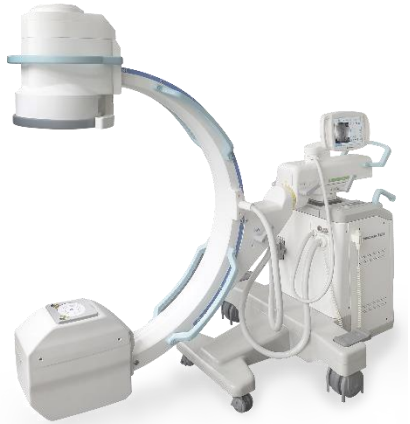
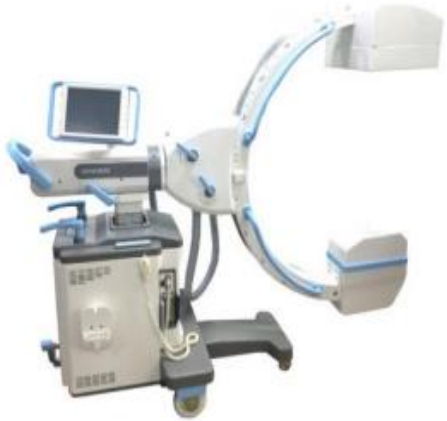
The OSCAR 15 & OSCAR 15i, C-Arm Mobile are used for providing fluoroscopic and radiographic images of patient anatomy, especially during special procedures in a hospital or medical clinics. The fluoroscopic mode of operation is very useful to the attending physician to see the images on real time without the need to develop individual films. These devices are intended to visualize anatomical structures by converting a pattern of x-radiation into a visible image through electronic amplification.

The OSCAR 15 & OSCAR 15i consist of the X-ray tube, X-ray tube assembly, X-ray controller, Image receptor and some accessories with no wireless function. The difference between OSCAR 15 and OSCAR 15i is only image acquisition parts. (An Flat Panel Detector (FPD) is applied to OSCAR 15, and an Image instensifier is applied to OSCAR 15i.)

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

OSCAR 15 & OSCAR 15i are a mobile fluoroscopy system designed to provide fluoroscopic and spot film images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac and critical care. The system may be used for other imaging applications at the physician's discretion. OSCAR 15 and OSCAR 15i are indicated only for adult patients.

7. <u>Substantial equivalence chart</u> [21 CRF 807.92(a) (6)]

	Proposed device		**Predicate device**
	OSCAR 15	**OSCAR 15i**	**OSCAR 15**
Manufacturer	GENORAY Co., Ltd.		GENORAY Co., Ltd.
510(k) No.	-		K172180
Classification Name	Interventional Fluoroscopic X-Ray System		Interventional Fluoroscopic X-Ray System
			

	Proposed device		Predicate device
	OSCAR 15	**OSCAR 15i**	**OSCAR 15**
Indications for use	OSCAR 15 & OSCAR 15i are a mobile fluoroscopy system designed to provide fluoroscopic and spot film images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac and critical care. The system may be used for other imaging applications at the physician's discretion. OSCAR 15 and OSCAR 15i are indicated only for adult patients.		OSCAR 15 is a mobile fluoroscopy system designed to provide fluoroscopic and spot film images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac and critical care. The system may be used for other imaging applications at the physician's discretion..
Max. output power	15 kW	15 kW	15 kW
X-ray Tube	Rotating tube	Rotating tube	Rotating tube
	Large : 0.6 mm Small : 0.3 mm	Large : 0.6 mm Small : 0.3 mm	Large : 0.6 mm Small : 0.3 mm
	High Frequency Inverter	High Frequency Inverter	High Frequency Inverter

	Proposed device		Predicate device
	OSCAR 15	**OSCAR 15i**	**OSCAR 15**
Generator	[Radiography] ● Output kV, mAs : 120kV @ 100mAs (max.) ● kV range : 40kV ~ 120kV, Step: 1kV ● mAs range : 0.4mAs ~ 100mAs, 24 Steps (Snapshot: 1.0mA ~ 50.0mA) [Fluoroscopy] ● Output kV, mA : 120kV, 4mA (max.) ● kV range : 40kV ~ 120kV, step: 1kV ● mA range - Small focus : 0.2mA ~ 6.0mA, Continuous mode 2.0mA ~ 10.0mA, Pulsed mode - Large focus : 1.0mA ~ 20.0mA, Continuous mode 3.0mA ~ 50.0mA, Pulsed mode	[Radiography] ● Output kV, mAs : 120kV @ 100mAs (max.) ● kV range : 40kV ~ 120kV, Step: 1kV ● mAs range : 0.4mAs ~ 100mAs, 24 Steps (Snapshot: 1.0mA ~ 50.0mA) [Fluoroscopy] ● Output kV, mA : 120kV, 4mA (max.) ● kV range : 40kV ~ 120kV, step: 1kV ● mA range - Small focus : 0.2mA ~ 6.0mA, Continuous mode 2.0mA ~ 10.0mA, Pulsed mode - Large focus : 1.0mA ~ 20.0mA, Continuous mode 3.0mA ~ 50.0mA, Pulsed mode	[Radiography] ● Output kV, mAs : 120kV @ 100mAs (max.) ● kV range : 40kV ~ 120kV, Step: 1kV ● mAs range : 0.4mAs ~ 100mAs, 24 Steps [Fluoroscopy] ● Output kV, mA : 120kV, 4mA (max.) ● kV range : 40kV ~ 120kV, step: 1kV ● mA range - Small focus : 0.2mA ~ 6.0mA, Continuous mode 1.0mA ~ 10.0mA, Pulsed mode - Large focus : 1.0mA ~ 20.0mA, Continuous mode 1.0mA ~ 48.0mA, Pulsed mode

	Proposed device		Predicate device
	OSCAR 15	**OSCAR 15i**	**OSCAR 15**
Detector	**FXDD-1212GA (Flat Panel Detector)** ● Active image area : 296.96 x 296.96 mm ● Maximum resolution: 3.4 lp/mm ● Type : TFT ● Pixel sampling resolution : 16 bits ● Pixel pitch : 145 µm ● MTF: 78% (0.5 lp/mm) ● DQE: 60% (0.5 lp/mm) ● Scintillator : CsI Previously cleared under K180473.	**E5830SD-P4A (Image Intensifier)** ● Size of incident surface : 230 mm (9”) ● Conversion factor 29 (cd/m^2)/(uGy/s) 250 (cd/m^2)/(uGy/s) ● Rated of contrast 30:1 (10% Area Contrast) 19:1(10mm Dia. Contrast) ● DQE: 65% ● Resolution 9” - 52 (Lp/cm typ.) 6” – 58 (Lp/cm typ.) 4.5”- 68 (Lp/cm typ.) ● Out image diameter : 25 ±0.5 mm Previously cleared under K211780.	**DualRay-Q (Flat Panel Detector)** ● Active image area : 260 x 256 mm ● Central Resolution: 4.6 lp/mm ● Type : CMOS ● Pixel sampling resolution : 14 bits ● Pixel pitch : 100 µm ● MTF: 56% ● DQE: 59% ● Scintillator : CsI
Dimensions	SID : 1000 mm	SID : 1000 mm	SID : 1000 mm
	C-arc Panning : ±12.5˚	C-arc Panning : ±12.5˚	C-arc Panning : ±12.5˚
	C-arc Orbital angle : 150˚	C-arc Orbital angle : 135˚	C-arc Orbital angle : 155˚
	C-arc up/down range : 500 mm	C-arc up/down range : 500 mm	C-arc up/down range : 500 mm
	C-arc back/forward range : 200 mm	C-arc back/forward range : 200 mm	C-arc back/forward range : 200 mm

When compared to the predicate device (K172180), the proposed devices presented in this submission has the identical

- Indications for use
- Maximum output power
- X-ray source

The differences between proposed device and predicate device (K172180) are change of detector, addition of New model OSCAR 15i.

A new model, OSCAR 15i has been added to the predicate device (K172180).
The difference between OSCAR 15i and predicate device (K172180) is image acquisition parts. An Flat Panel Detector (FPD) is applied to OSCAR 15, and an Image instensifier is applied to OSCAR 15i. Brief description of technology and conversion principle of x-ray signal to image acquired of whole detector chain through an Image intensifier is below. Total conversion mechanism is that x-ray signal irradiated to the surface of the IIT is converted into a pixel value of a digital image in proportion to its amount. That of conversion method described, signals are transferred by several steps by the IIT and the CCD camera attached to IIT output window. FPDs designed specifically for fluoroscopic use provide image quality and dose efficiency generally superior to the II systems that they replace, except at the lowest fluoro dose levels. Advantages include excellent image uniformity, no geometric distortion, no veiling glare or vignetting, and small, thin physical size for improved patient accessibility. Since a detector different from the predicate device is applied to the proposed device, the performance related to image quality is also different. The image performance was evaluated according to the IEC standard through performance bench testing. The performance bench testing demonstrated that these differences do not raise any questions of safety and effectiveness in comparison with the predicate device. Furthermore, clinical images have been evaluated by a licensed radiologist and the results confirmed the sufficient diagnostic quality to provide accurate information.

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

OSCAR 15 & OSCAR 15i have been successfully completed verification and validation testing per GENORAY quality system as well engineering bench testing in support of 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 60601-2-28, IEC 60601-2-43, IEC 60601-2-54, IEC 62366. Also, OSCAR 15 & OSACR 15i comply with all applicable 21 CFR performance standards (21 CFR 1020.30, CFR 1020.31, 1020,32)

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 OSCAR 15 & OSACR 15i 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 and clinical evaluation indicates that the new device is as safe and effective as the predicate device.

9. Conclusion

In reference to the comparison information provided in substantial equivalence chart, and the most of functions and electronic features are similar with predicate device. We believe that the OSCAR 15 & OSCAR 15i are safe and effective as predicate device, and have no new indication for use. Therefore, OSCAR 15 & OSCAR 15i are substantially equivalent to predicate device.