February 9, 2018

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

Re: K172180
Trade/Device Name: Oscar 15
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA
Dated: December 28, 2017
Received: January 2, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K172180

Device Name

OSCAR 15

Indications for Use *(Describe)*

OSCAR 15 is a mobile fluoroscopy system is 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.

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.

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510(k) Summary

Date of Summary Preparation: July. 04, 2017

1. Submitter and US Official Correspondent

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2. Establishment Registration Number

3005843418

3. Device Information

Trade/Device Name:	OSCAR 15
Regulation Name:	Fluoroscopic X-ray System
Classification Name:	Interventional Fluoroscopic X-Ray System
Product Code:	OWB / Interventional Fluoroscopic X-Ray System
Subsequence product code:	JAA / System, X-Ray, Fluoroscopic, Image-Intensified
Device Class:	Class II per regulation 21 CFR 892.1650

4. Predicate Device (Equivalent Legally Marketed Device)

Manufacturer:	GENORAY Co., Ltd
Device Name:	ZEN-7000
510(k) Number:	K140041 (Decision Date – November 28, 2014)
Classification:	Interventional Fluoroscopic X-Ray System/OWB Image Intensified Fluoroscopic X-Ray System, Mobile/OXO System, X-Ray, Fluoroscopic, Image-Intensified/JAA Class II per regulation 21 CFR 892.1650

5. Description of the Device

OSCAR 15 is consist of X-ray Tube, X-ray tube assembly, x-ray controller, detector and accessories. There is no wireless function in this device.

The OSCAR 15, C-Arm Mobile is the device intended to visualize anatomical structures by converting a pattern of x-radiation into a visible image through electronic amplification.
This device is used for providing fluoroscopic and radiographic images of patient anatomy, especially during the 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.

6. Indications for use (intended use)

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.

7. Substantial equivalence chart

Name	Proposed device OSCAR 15	Predicate device ZEN-7000
Manufacturer	GENORAY Co., Ltd.	GENORAY Co., Ltd.
510(k) No.	-	K140041
Indications for use	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.	ZEN-7000 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, critical care and emergency room procedures. The system may be used for other imaging applications at the physician's discretion.

Name	Proposed device OSCAR 15	Predicate device ZEN-7000
Manufacturer	GENORAY Co., Ltd.	GENORAY Co., Ltd.
510(k) No.	-	K140041
Generator	High Frequency Inverter	High Frequency Inverter
Max. output power	15 kW	5 kW 15 kW (Optional)
X-ray Tube	Rotating tube	Rotating tube
	Large : 0.6 mm Small : 0.3 mm	Large : 0.6 mm Small : 0.3 mm
Fluoroscopy	40-120 kV / 0.2-6.0 mA	40-120 kV/ 0.2-6.0 mA
Pulsed Fluoroscopy	1 mA to 48 mA	1 mA to 20 mA(5kW) 1 mA to 48 mA(15kW)
Radiography	40-120 kV / 0.4-100 mAs	40-120 kV / 1-100 mAs
Detector	Active image area : 260 x 256 mm Central Resolution 4.6 lp/mm Contrast Ratio (10%) : 30:1 Type : CMOS Resolution : 2600 x 2560 Pixel sampling resolution : 14 bits Pixel pitch : 100 μm MTF: 56% DQE: 59% Scintillator : CsI	9″ (9″/6″/4.5″) ● Minimum central resolution (at the monitor): -9″ (23cm): 2.2 lp/mm -6″ (15cm): 2.8 lp/mm -4.5″ (11cm): 3.0 lp/mm ● DQE: 65% (typical) 12″ (12″/9″/6″) ● Minimum central resolution (at the monitor): -12″ (31cm): 1.6 lp/mm -9″ (23cm): 2.0 lp/mm -6″ (15cm): 2.5 lp/mm ● DQE: 65% (typical)
Dimensions	SID : 1000 mm	SID : 1000 mm
	Panning Rotation: ±12.5˚	Panning Rotation: ±12.5˚
	Orbital Rotation: 155˚	Orbital Rotation: 135˚
	Vert. Travel: 500 mm	Vert. Travel: 500mm
	Horiz. Travel: 200 mm	Horiz. Travel: 200mm

The proposed OSCAR 15 is based on the predicate device, ZEN-7000(K140041). The generator is similar to predicate device with output power, 15 kW. Also X-ray tube of OSCAR 15 is same with predicate device.

The difference between OSCAR 15 and predicate device is the options of Image acquisition parts. OSCAR 15 is Flat panel detector and predicate device is Image Intensifier. As mentioned in the comparison table, predicate device DQE is higher than OSCAR 15. However, predicate device DQE is the DQE of the image intensifier itself. In general, when image intensifier is combined with CCD camera the DQE decreases. In conclusion, the DQE of the complete predicate device is 51%. So the DQE of the OSCAR 15 is more effective and safety than predicate device. Also flat panel detector type has excellent image uniformity, no geometric distortion, no veiling glare or vignetting, small and thin physical size as compared to the Image Intensifier type.

The OSCAR 15 is substantially equivalent to the predicate device, ZEN-7000(K140041).

8. Safety, EMC and Performance data comparison to Predicate

OSCAR 15 complies with industry standards such as IEC 60601-1 Series and 21 CFR 1020.30, 21 CFR 1020.31 and 21 CFR 1020.32 to minimize electrical, mechanical and radiation hazards.

- Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, IEC 60601-1-3, IEC 60601-2-28, IEC 60601-2-43 and IEC 60601-2-54 were performed.
- EMC testing was conducted in accordance with standard IEC 60601-1-2.
- OSCAR 15 meets the EPRC standards (21 CFR 1020.30, 31, 32).
- FDA guidance “guidance for SSXI devices”, “guidance for the Content of Premarket Submissions for Software Contained in Medical devices”, and “content of premarket submissions for management of cyber security” was performed for OSCAR 15.

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 is safe and effective as predicate device, and has no new indication for use. Therefore, OSCAR 15 is substantially equivalent to predicate device.