August 17, 2018

GENORAY Co., Ltd.
% Ms. Kaitlynn Min
Business Development
GENORAY America Inc.
147 E. Bristol Lane
ORANGE CA 92780

Re: K181943
Trade/Device Name: OSCAR (OSCAR Prime, OSCAR Classic)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA
Dated: July 5, 2018
Received: July 20, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181943

Device Name
OSCAR (OSCAR Prime, OSCAR Classic)

Indications for Use *(Describe)*
OSCAR 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, and stone localization.

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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Exhibit 5 510(k) Summary

Date of Summary Preparation: July. 05, 2018

1. Submitter and US Official Correspondent

Submitter : GENORAY Co., Ltd.

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Email: kaitlynn@genorayamerica.com

2. Establishment Registration Number

3005843418

3. Device Information

Trade/Device Name:	OSCAR OSCAR Prime, OSCAR Classic
Regulation Name:	Image-Intensified 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-2090 Pro
510(k) Number:	K091918 (Decision Date – October 07, 2009)
Classification Name:	Image –Intensified Fluoroscopic X-Ray System
Primary Product Code:	OWB/Interventional Fluoroscopic X-ray System
Secondary product code:	JAA / system, x-ray, fluoroscopic, image-intensified
	OXO/ image-intensified fluoroscopic x-ray system, mobile
Device Class:	Class II per regulation 21 CFR 892.1650

5. Description of the Device

OSCAR Prime and OSCAR Classic are classified according to the option of image acquisition parts. Flat panel detector is OSCAR Prime, and Image intensifier is OSCAR Classic. And they are called OSCAR as the brand name.

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

The OSCAR, 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

OSCAR 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, and stone localization. The patient group using OSCAR is all except children.

7. Substantial equivalence chart

Name	Proposed device OSCAR	Predicate device ZEN-2090 Pro
Manufacturer	GENORAY Co., Ltd.	GENORAY Co., Ltd.
510(k) No.	-	K091918
Indications for use	OSCAR 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 patient group using OSCAR is all except children.	ZEN-2090 Pro is a mobile digital C-arm designed to provide fluoroscopic and radiographic images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, orthopedic, neurologic, stone localization, critical care and emergency room procedures i.e. surgical interventions needing X-ray imaging and/or guidance and interventions inside and outside the operating room.
Generator	High Frequency Inverter	High Frequency Inverter
Max. output power	4.5kW	2.2kW

<table>
<tr><td rowspan="2">X-ray tube</td><td colspan="2">Stationary tube</td><td>Stationary tube</td></tr>
<tr><td colspan="2">Large: 1.4 / Small: 0.5</td><td>Large : 1.5 mm / Small : 0.5 mm</td></tr>
<tr><td rowspan="2">Detector</td><td>OSCAR Prime (Flat panel)</td><td>OSCAR Classic (Image intensifier)</td><td>ZEN-2090 Pro (Image Intensifier)</td></tr>
<tr><td>Option A: GFD-200 (DualRay-Q)
(Cleared under K172180)
● Active image area : 260 x 256 mm
● Central Resolution :4.6 lp/mm
● Type : CMOS
● Resolution : 2600 x 2560
● Pixel sampling resolution : 14 bits
● Pixel pitch : 100 μm
● MTF: 56%
● DQE: 59%
● Scintillator : CsI</td><td>Option A: E5830SD-P4A
(Cleared under K140041)
● Active image area : 9” (9″/6″/4.5″)
● Min. Central Resolution at the monitor:
- 9” (23cm): 2.2 lp/mm
- 6” (15cm): 2.8 lp/mm
- 6” (15cm): 3.0 lp/mm
● DQE: 65% (typically)</td><td>E5830SD-P4A
● Active image area : 9” (9″/6″/4.5″)
● Min. Central Resolution at the monitor:
- 9” (23cm): 2.2 lp/mm
- 6” (15cm): 2.8 lp/mm
- 6” (15cm): 3.0 lp/mm
● DQE: 65% (typically)</td></tr>
<tr><td>Option B: VIVIX-D 0909G
● Active image area : 229.12 x 229.12mm
● Central Resolution : 2.7 lp/mm
● Type : a-Si TFT
● Resolution : 2600 x 2560
● Pixel sampling resolution : 16 bit
● Pixel pitch : 179 μm
● MTF: 45%
● DQE: 45%
● Scintillator : CsI</td><td>Option B: TH 9438 QX
(Cleared under K140041).
● Active image area : 9” (9″/6″/4.5″)
● Min. Central Resolution at the monitor:
- 9” (23cm): 2.2 lp/mm
- 6” (15cm): 2.8 lp/mm
- 6” (15cm): 3.0 lp/mm
● DQE: 65% (typically)</td><td></td></tr>
</table>

Fluoroscopy	40-120 kV / 0.2-6.0 mA	40-110 kV/ 0.2-6.0 mA
Pulsed Fluoroscopy	0.2 - 10.0 mA	0.2-6.0 mA
Radiography	40-120 kV / 0.6-200 mAs	40-110 kV / 0.4-100 mAs
Dimensions	SID : 1000 mm	SID : 960 mm
	Panning Rotation: ±12.5˚	Panning Rotation: ±12.5˚
	Orbital Rotation: 155˚	Orbital Rotation: 120˚
	Vert. Travel: 500 mm	Vert. Travel: 400mm
	Horiz. Travel: 200 mm	Horiz. Travel: 200mm

The proposed OSCAR is based on the predicate device, ZEN-2090 Pro (K091918). There are several difference between OSCAR (Prime, Classic) and predicate device (ZEN-2090 Pro) is the options of Image acquisition parts. OSCAR Prime is the flat panel detector and predicate device is Image Intensifier. As mentioned in the comparison table, predicate device DQE is higher than OSCAR Prime. 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 Prime 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 is substantially equivalent to the predicate device, ZEN-2090 Pro (K091918).

8. Safety, EMC and Performance data comparison to Predicate

OSCAR 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 60601-1-6, IEC 60601-2-28, IEC 60601-2-43, IEC 60601-2-54 and IEC 62366 were performed.
- EMC testing was conducted in accordance with standard IEC 60601-1-2.
- OSCAR meets the EPRC standards (21 CFR 1020.30, 31, 32).
- FDA guidance "guidance for SSXI devices", and "guidance for the Content of Premarket Submissions for Software Contained in Medical devices", was performed for OSCAR.

The software features has been changed compare to predicate device as below:

- Enhance Image Calibration function.
- Display exposure modes shows on the LCD touch panel.
- Add Angiography functions.

Changes to the predicate device software were tested and they do not affect the device safety and effectiveness. Also, the device software is moderate level of concern.

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