DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

GENORAY Co., Ltd.
% Ms. Kaitlynn Min
Business Development Manager
GENORAY America, Inc.
3002 Dow Avenue, Suite 420
TUSTIN CA 92780

December 9, 2014

Re: K140041
Trade/Device Name: Fluoroscopic X-ray System (Models: ZEN-7000)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, OXO, JAA
Dated: October 29, 2014
Received: October 30, 2014

Dear Ms. Min:

This letter corrects our substantially equivalent letter of November 28, 2014.

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
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)*
K140041

Device Name
Fluoroscopic X-Ray System (Models: ZEN-7000)

Indications for Use *(Describe)*
ZEN-7000 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, critical care and emergency room procedures. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"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

Date of Summary Preparation: January 2, 2014

1. Submitter and US Official Correspondent:

1.1 Submitter

Submitter:	GENORAY Co., Ltd.
Address:	#512, Byucksan Technopia, 434-6, Sangdaewon 1-dong, Jungwon-gu, Seongnam-city, Gyeonggi-do, 462-716, Korea
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1.2 Official Correspondent (U.S): Kaitlynn Min - Business Manager

Correspondent:	GENORAY America Inc.
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Telephone No.:	714-289-8020
Fax:	714-786-8919
Email:	kaitlynn@genorayamerica.com

2. Establishment Registration Number

3005843418

3. Device Information

Proprietary/Trade Name:	ZEN-7000
Common/Usual Name:	Fluoroscopic X-Ray System
Classification Name:	System, X-Ray, Fluoroscopic, Image-Intensified
Product Code:	Primary product code OWB Secondary product code JAA, OXO
Device Class:	Class II per regulation 21 CFR 892.1650

4. Legally Marketed Predicate Device

Manufacturer:	GENORAY Co., Ltd.
Trade Name:	ZEN-7000
510(k) Number:	K103425 (Decision Date – Mar 29, 2011)
Classification Name:	System, X-Ray, Fluoroscopic, Image-Intensified
Product Code:	Primary product code OWB Secondary product code JAA, OXO

Manufacturer:	GE Healthcare Surgery
Trade Name:	OEC 9900 Elite
510(k) Number:	K082781 (Decision Date – May 01, 2009)
Classification Name:	System, X-Ray, Fluoroscopic, Image-Intensified
Product Code:	Primary product code OWB Secondary product code JAA, OXO

5. Description of the Device

ZEN-7000 mobile fluoroscopy system is an image intensified fluoroscopic system consisting of two mobile units: a Mainframe (C-Arm) and a Workstation. The Mainframe (C-Arm) is comprised of a high voltage generator, x-ray control, and a "C" shaped apparatus, which supports an X-ray tube and an image intensifier. The Mainframe is designed to perform linear and rotational motions that allow the user to position the x-ray imaging components at various angles and distances with respect to the patient. The Workstation is a mobile platform that supports image display monitors and recording devices.

6. Indications for use

ZEN-7000 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, critical care and emergency room procedures. The system may be used for other imaging applications at the physician′s discretion.

7. Substantial Equivalence Chart

Name	**Proposed device GENORAY Fluoroscopic X-Ray System, ZEN-7000**	**Predicate device GENORAY Fluoroscopic X-Ray System, ZEN-7000 K103425**	**Predicate device GE Healthcare Surgery Fluoroscopic X-Ray System OEC 9900 Elite K082781**
Manufacturer	GENORAY Co., Ltd	GENORAY Co., Ltd	GE Healthcare Surgery
Indications for use	ZEN-7000 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, critical care and emergency room procedures. The system may be used for other imaging applications at the physician′s discretion.	ZEN-7000 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, critical care and emergency room procedures. The system may be used for other imaging applications at the physician′s discretion.	The OEC 9900 Elite 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, critical care and emergency room procedures. The system may be used for other imaging applications at the physician′s discretion.
Generator	High Frequency Inverter	High Frequency Inverter	High Frequency Inverter
Max. output power	5 kW 15kW(Optional)	5 kW	15kW
X-ray tube	Rotating tube Large: 0.6 mm Small: 0.3 mm	Rotating tube Large: 0.6 mm Small: 0.3 mm	Rotating tube 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	40-120 kV / 0.2- 10 mA

Pulsed Fluoroscopy	1 mA to 20 mA(5kW) 1 mA to 48 mA(15kW)	1 mA to 20 mA	0.2 mA to 40 mA
Radiography	40-120 kV / 1-100 mAs	40-120 kV / 0.4-100 mAs	40~120 kV / 1-300mAs
TV Camera	CCD Type	CCD Type	CCD Type
Image Intensifier	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)	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)	9″(9″/6″/4.5″) • Minimum central resolution (at the monitor): -9″ (23cm): 2.1 lp/mm -6″ (15cm): 2.9 lp/mm -4.5″ (11cm): 3.4 lp/mm • DQE: 65% (typical) 12″(12″/9″/6″) • Minim m central resolution (at monitor): -12″ (31cm): 1.5 lp/mm -9″ (23cm): 2.1 lp/mm -6″ (15cm): 2.6 lp/mm • DQE: 65% (typical)
Dimensions	SID: 1000mm	SID: 1000mm	SID: 1000mm
	Free space: 786 mm	Free space: 750mm	Free space: 787mm
	Depth: 730 mm	Depth: 700 mm	Depth: 660mm
	C-arm wig wag: ±12.5°	C-arm wig wag: ±12.5°	C-arm wig wag: ±20°
	Orbital Rotation: 135°	Orbital Rotation: 135°	Orbital Rotation: 115°
	Vert. Travel: 500mm	Vert. Travel: 450mm	Vert. Travel: 457mm
	Horiz. Travel: 200mm	Horiz. Travel: 200mm	Horiz. Travel: 203mm

The proposed ZEN-7000 is based on the predicate device, ZEN-7000(k103425). The generation is similar to predicate devices with optional output power, 15kW. And Image intensifier has 9″ and 12″ sizes as predicate device OEC 9900 Elite (K082781).

The ZEN-7000 is substantially equivalent to the predicate devices, ZEN-7000(k103425) and OEC 9900 Elite (K082781).

8. Safety and Effectiveness, comparison to Predicate

ZEN-7000 complies with industry standards such as IEC 60601-1 Series and 21 CFR 1020.30 and 21 CFR 1020.31 to minimize electrical, mechanical and radiation hazards. The new device modified from the predicate device was completed in accordance with GENORAY quality management system design controls.

- 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.

- FDA Guidance ″Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" was performed.

- ZEN-7000 meets the EPRC standards (21 CFR 1020.30, 31).

- ZEN-7000 also meets the provisions of NEMA PS 3.1-3.18, Digital Imaging and Communications in Medicine (DICOM) Set.

All test results were satisfactory and the result of bench and clinical evaluation indicates that the ZEN-7000 is as safe and effective as the predicate devices.

9. Conclusion

ZEN-7000 has the same indication for use as the predicate devices. And there have been no changes implemented in the modifications to the predicate ZEN-7000 and OEC 9900 Elite that impact either the fundamental technology or the indications for use. The New device outlined in this Premarket Notification is substantially equivalent to the currently commercially available predicate devices.