Exhibit 5 **510(k) Summary**

MAR 2 9 2011

K103425

Fluoroscopic X-Ray System / Model: ZEN-7000

1. Company and Correspondent making the submission:

1.1 Submitter and US Official Correspondent

Submitter:	GENORAY Co., Ltd.
Address:	#512, Byucksan Technopia, 434-6, Sangdaewon 1-dong, Jungwon-gu, Seongnam-city, Gyeonggi-do, 462-716, Korea
Telephone No.:	+82-31-740-4100
Fax:	+82-31-737-8025

1.2 Official Correspondent (U.S): Jae Kim - Business Manager

Correspondent:	GENORAY America Inc.
Address:	1073 N. Batavia St. Orange, CA 92867, USA
Telephone No.:	714-289-8020
Fax:	714-453-9661
Email:	jae@genorayamerica.com

2. Establishment Registration Number

3005843418

3. Device Information

Proprietary/Trade Name:	Fluoroscopic X-Ray System / Model: ZEN-7000
Common/Usual Name:	Fluoroscopic X-Ray System
Classification Name:	System, X-Ray, Fluoroscopic, Image-Intensified / System, X-Ray, Mobile
Product Code:	JAA / IZL
Device Class:	Class II per regulation 21 CFR 892.1650 / Class II per regulation 21 CFR 892.1720

4. Equivalent Legally Marketed Device

Manufacturer:	GE OEC Medical Systems, Inc
Device Name:	OEC 9800 Plus
510(k) Number:	K021049 (Decision Date – April 17, 2002)
Classification:	System, X-Ray, Fluoroscopic, Image-Intensified: JAA, Class II per regulation 21 CFR 892.1650 / System, X-Ray, Mobile: IZL, Class II per regulation 21 CFR 892.1720

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.

5.1 Specification of ZEN-7000

- Generator : High Frequency Inverter
- Max. output power : 5 kW
- X-ray tube : Rotating tube
- Fluoroscopy : 40~120 kV / 0.2~6.0 mA
- Radiography : 40~120 kV / 20 mA
- TV Camera : CCD Type
- Image Intensifier : 9"(9"/6"/4.5")
- C-arm wig wag : ±12.5°
- Orbit. Rotation : 135°
- Horiz. Travel : 200 mm
- Vert. Travel : 450 mm

6. Indications for use

ZEN-7000 Digital mobile Imaging system is designed to provide fluoroscopic and spot-film imaging 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. Safety and Effectiveness, comparison to Predicate

The result of bench and clinical evaluation indicates that the new device is as safe and effective as the predicate devices.

8. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided the above comparison table, the GENORAY Co., Ltd., concludes that the Fluoroscopic X-Ray System (Model: ZEN-7000) is safe and effective and substantially equivalent to the predicate device as described above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

GENORAY Co., Inc.
% Mr. Jae Kim
Business Development Manager
GENORAY America, Inc.
1073 N. Batavia St.
ORANGE CA 92867

MAR 2 9 2011

Re: K103425
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: JAA and IZL
Dated: February 10, 2011
Received: February 18, 2011

Dear Mr. Kim:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

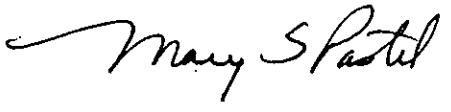
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Exhibit 4 Indications for use

510(k) number (if known): K103425

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

Indications for Use:

ZEN-7000 Digital mobile Imaging system is designed to provide fluoroscopic and spot-film imaging 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.

Prescription Use ___V___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103425