March 9, 2022

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

Re: K211780
Trade/Device Name: ZEN-2090 Turbo
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, OXO
Dated: February 17, 2022
Received: February 18, 2022

Dear Ms. 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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K211780

Device Name
ZEN-2090 Turbo

Indications for Use *(Describe)*

ZEN-2090 Turbo, C-Arm mobile is used for providing fluoroscopic and radiographic images of patient anatomy in a hospital or medical clinics.

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: June. 04, 2021

1. Submitter and US Official Correspondent

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2. Establishment Registration Number

3005843418

3. Device Information

Trade/Device Name:	ZEN-2090 Turbo
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
	OXO / Image-intensified fluoroscopic x-ray system, mobile
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:	Interventional 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

ZEN-2090 Turbo, C-arm mobile is used for providing fluoroscopic image of patient anatomy, especially during diagnostic, surgical and interventional procedures. 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.

ZEN-2090 Turbo is consisting of the X-ray tube, X-ray tube assembly, X-ray controller, XTV Camera and some accessories.

6. Indications for use

ZEN-2090 Turbo, C-Arm mobile is used for providing fluoroscopic and radiographic images of patient anatomy in a hospital or medical clinics.

7. Substantial equivalence chart

Name	Proposed device ZEN-2090 Turbo	Predicate device ZEN-2090 Pro
Manufacturer	GENORAY Co., Ltd.	GENORAY Co., Ltd.
510(k) No.	-	K091918
Indications for use	ZEN-2090 Turbo, C-Arm mobile is used for providing fluoroscopic and radiographic images of patient anatomy in a hospital or medical clinics.	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	2.0kW	2.2kW
X-ray tube	Stationary tube	Stationary tube
	0.6 mm	Large : 1.5 mm / Small : 0.5 mm

Name	Proposed device ZEN-2090 Turbo	Predicate device ZEN-2090 Pro
Detector (Image Intensifier)	**E5830SD-P4A** ● Active image area : 9” (9″/6″/4.5″) ● Min. Central Resolution at the monitor: - 9” (23cm): 2.2 lp/mm - 6” (16cm): 2.8 lp/mm - 4.5” (12cm): 3.0 lp/mm ● DQE: 65%	**E5830SD-P4A** ● Active image area : 9” (9″/6″/4.5″) ● Min. Central Resolution at the monitor: - 9” (23cm): 2.2 lp/mm - 6” (16cm): 2.8 lp/mm - 4.5” (12cm): 3.0 lp/mm ● DQE: 65%
Fluoroscopy	40-110 kV / 0.2-12.0 mA	40-110 kV/ 0.2-6.0 mA
Pulsed Fluoroscopy	1.0 - 24.0 mA	0.2-6.0 mA
Dimensions	SID : 960 mm	SID : 960 mm
	Panning Rotation: ±12.5˚	Panning Rotation: ±12.5˚
	Orbital Rotation: 135˚	Orbital Rotation: 120˚
	Vert. Travel: 500 mm	Vert. Travel: 400mm
	Horiz. Travel: 200 mm	Horiz. Travel: 200mm

The proposed ZEN-2090 Turbo is based on the predicate device, ZEN-2090 Pro (K091918).

ZEN-2090 Pro supports both Radiography mode and Fluoroscopy mode, while ZEN-2090 Turbo supports only Fluoroscopy mode.

For Fluoroscopy mode, ZEN-2090 Pro consists of single dose mode, and the maximum X-ray output power is 440W at 110kV, 4mA and the focal size is 0.5 mm with small focus. This is the same for both Continuous Fluoroscopy mode and Pulsed Fluoroscopy mode.

ZEN-2090 Turbo can select 3 dose modes (low, normal, high mode), and the focal size is 0.6 mm with single focus.
Normal mode of ZEN-2090 Turbo in Continuous Fluoroscopy mode is the same as ZEN-2090 Pro, and high mode is limited to 880W at 110kV, 8mA, it is the twice than normal mode.
ZEN-2090 Turbo in Pulsed Fluoroscopy mode is set higher than ZEN-2090 Pro in both normal and high mode.
Among them, high mode is limited to 2000W at 110kV, 18.1mA.

According to the above, ZEN-2090 Turbo is 2 times more than ZEN-2090 Pro in Continuous Fluoroscopy mode, and about 5 times difference in Pulsed Fluoroscopy mode.
Therefore, we have justified that ZEN-2090 Turbo has better image quality than predicate device, ZEN-2090 Pro (K091918).

8. Safety, EMC and Performance data comparison to Predicate

ZEN-2090 Turbo has 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 and IEC 62366. Also all applicable 21 CFR performance standards (21 CFR 1020.30, 1020.31, 1020.32) are met.

And Software verification testing of the functional requirements as well as performance and safety has been performed to verify that all the requirements of System Requirements Specification as well as the safety risk control measures from the Detailed Risk Management Matrix and the Privacy and Security requirements and mitigations have been implemented. 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" to ensure substantial equivalence.
Results demonstrated that all executed verification tests were passed.

Non-clinical validation testing has been performed to validate that ZEN-2090 Turbo conforms 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 ZEN-2090 Turbo is safe and effective as predicate device, and has no new indication for use. Therefore, ZEN-2090 Turbo is substantially equivalent to predicate device.