April 2, 2026

GENORAY Co., Ltd
℅ Simon Jo
General Manager
Genoray America Inc.
1220 N Simon Circle, Unit B
ANAHEIM, CA 92806

Re: K252229
Trade/Device Name: BELLIGER ACE
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: July 14, 2025
Received: March 3, 2026

Dear Simon Jo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

for

Lu Jiang Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252229

Device Name
BELLIGER ACE

Indications for Use *(Describe)*
It is intended for use in providing fluoroscopic and digital spot images of patient populations during diagnostic, interventional, and surgical procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K252229

510(k) Summary

Prepared on: 2026-03-03

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	GENORAY Co., Ltd
Applicant Address	60, Dunchon-daero 541beon-gil, Jungwon-gu Seongnam-si Gyeonggi 13212 Korea, Republic of
Applicant Contact Telephone	+821088336418
Applicant Contact	Mr. Dongwon Kang
Applicant Contact Email	dwkang@genoray.com
Correspondent Name	GENORAY AMERICA INC.
Correspondent Address	1220 N Simon Circle Unit B Anaheim CA 92806 United States
Correspondent Contact Telephone	+1-714-581-3604
Correspondent Contact	Mr. Simon Jo
Correspondent Contact Email	simon@genorayamerica.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	BELLIGER ACE
Common Name	Interventional Fluoroscopic X-Ray System
Classification Name	Image-intensified Fluoroscopic X-Ray System
Regulation Number	892.1650
Product Code(s)	OWB, JAA

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K181943	OSCAR Prime	OWB

Device Description Summary

21 CFR 807.92(a)(4)

BELLIGER ACE is Fluoroscope X-ray system that is designed to provide fluoroscopic and radiographic images of the patient during diagnostic, surgical and interventional procedures. The fluoroscopic mode of operation is very useful to the attending physician to see the images in real-time without the need to develop individual films. BELLIGER ACE consists of the X-ray tube, X-ray tube assembly, X-ray controller, and Image receptor(Flat Panel Detector) with no wireless function and some accessories(Hand switch, Foot switch, Grid(option)).

It is to be used in health care facilities both inside and outside the operating room in a variety of procedures. For this reason, X-ray tube assembly of BELLIGER ACE have a degree of protection of IPX2, and footswitch have a degree of protection of IPX7 for protection against ingress of liquid. Also, if a power problem occurs such as blackout, BELLIGER ACE will cut off the power. Also, In case of emergency, push the emergency stop switch on the switch panel to stop the equipment.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

It is intended for use in providing fluoroscopic and digital spot images of patient populations during diagnostic, interventional, and surgical procedures.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use for BELLIGER ACE are the same as for the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The characteristics of the proposed device “BELLIGER ACE” is identical or similar to those of the predicate device regarding X-ray generation device characteristics including indications for use, exposure mode, input voltage, tube voltage, tube current, focal spot size, detector type, C-arm geometry. Minor design change regarding software and exterior is applied. And there is no significant difference between the proposed device and the predicate device that would adversely affect the use of the product. The subject device is substantially equivalent to the predicate device.

Second, the proposed device has same detector "OX/110-0514" as predicate device and additionally proposed device has D-068SBR. And it has the same type of detectors "CMOS(Flat Panel Detector) and a-Si TFT Flat Panel Detector".

Third, it has similar X-ray output power and C-arm geometry.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

List of IEC standards the device complies with:
1. IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
2. IEC 60601-1-2:2014+AMD1:2020 Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests
3. IEC TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
4. IEC 60601-1-3:2008+AMD1:2013+AMD2:2021 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
5. IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
6. IEC 60601-2-28:2017 Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
7. IEC 60601-2-43:2022 Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
8. IEC 60601-2-54:2022 Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

List of FDA Guidance documents utilized in the development of the device:
Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket SubmissionsGuidance for Industry and Food and Drug Administration Staff (Feb 2026)
Content of Premarket Submissions for Device Software FunctionsGuidance for Industry and Food and Drug Administration Staff (June 2023)
Solid State X-ray Imaging Devices: Guidance for Industry and Food and Drug Administration Staff (Sept 2016)

A clinical image evaluation was conducted with the BELLIGER ACE in accordance with the Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices: Guidance for Industry and Food and Drug Administration Staff issued on Sept. 1, 2016 (Section VII Clinical Considerations), and the images were reviewed by US Board-Certified Clinician.

BELLIGER ACE has the same indications for use as the predicate device. Any minor differences in the technical characteristics of the subject device have been successfully evaluated through the appropriate safety and performance testing.

According to the Clinical Image Evaluation Report, BELLIGER ACE's clinical images were sufficiently acceptable quality for usage of FLUOROSCOPE X-ray System and that the images are substantially equivalent to those from predicate device.

In conclusion, compared to the predicate device, subject device does not raise any new questions of safety and effectiveness. Therefore,

we confirmed that BELLIGER ACE is substantially equivalent to predicate device.