



November 16, 2023

Gemss Healthcare Co., Ltd.  
% Mr. Dave Kim  
RA Consultant  
Mtech Group LLC  
7505 Fannin St. Suite 610  
HOUSTON TX 77054

Re: K233200

Trade/Device Name: XPLUS 35 Series (XPLUS 35, XPLUS 35FD)  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image-intensified fluoroscopic x-ray system  
Regulatory Class: Class II  
Product Code: OWB, JAA, OXO  
Dated: September 22, 2023  
Received: September 28, 2023

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. 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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

The signature of Lu Jiang is written in a cursive script. To the right of the signature is a large, light blue watermark of the FDA logo.

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

## Indications for Use

510(k) Number (if known)  
K233200

Device Name  
XPLUS 35 Series (XPLUS 35, XPLUS 35FD)

Indications for Use (Describe)

XPlus 35 Series (XPLUS 35, XPLUS 35FD) are mobile digital C-arms designed to provide fluoroscopic and radiographic images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include endoscopy, orthopedic, neurologic, 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.

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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## **510(k) Summary**

### **K233200**

This summary of 510(K) - safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: November 15, 2023

#### **1. Applicant / Submitter**

- GEMSS HEALTHCARE CO., LTD.
- Address: 1F, 822, Bogwang-ro, Gwangtan-myeon, Paju-si, Gyeonggi-do, 10952, Republic of Korea
- Tel: +82-31-906-9017 Fax: +82-31-906-9019 Email:olivia@gemss.co.kr
- Official Correspondent (U.S): Dave Kim / Mtech Group LLC  
7505 Fannin St. Suite 610, Houston, TX 77054 / Tel) 1-713-467-2607 / davekim@mtechgroupllc.com

#### **2. Device Information**

- Trade/Device Name: XPLUS 35 Series (XPLUS 35, XPLUS 35FD)
- Regulation Number: 21CFR 892.1650
- Regulation Name: Image-Intensified Fluoroscopic X-ray System
- Device Class: Class II
- Product Code: OWB
- Subsequence product code: JAA, OXO

#### **3. Predicate Device**

- K Number: K091918
- Manufacturer: GENORAY Co., Ltd.
- Trade Name: ZEN-2090 Pro
- Regulation Number: 21CFR 892.1650
- Regulation Name: Image-Intensified Fluoroscopic X-ray System
- Device Class: Class II
- Product Code: OWB
- Subsequence product code: JAA, OXO

#### **4. Reference Device**

- K Number: K222080
- Manufacturer: SG HealthCare Co. Ltd.
- Trade Name: Garion
- Regulation Number: 21CFR 892.1650

- Regulation Name: Image-Intensified Fluoroscopic X-ray System
- Device Class: Class II
- Product Code: OWB

## 5. General Description

XPLUS 35 Series (XPLUS 35, XPLUS 35FD), C-arm mobile, is used for providing fluoroscopic image of patient anatomy, especially during diagnostic, surgical and interventional procedures.

XPLUS 35 Series (XPLUS 35, XPLUS 35FD) consist of X-ray tube, X-ray generator, C-arm including image receptor, monitor cart, medical monitor and accessories such as foot switch and hand switch.

### 1) C-arm

- X-ray tube: It converts high voltage currents into an X-ray through a generator.
- Image receptors: It translates the x-ray, which penetrates the patient's body, into the image signals.

### 2) Monitor cart

Main C-arm units and monitor cart are connected to each other with a cable. There is a main power cable to supply power to the monitor cart and main unit, which is not a battery type.

- Software: The displayed images can be edited and saved, and the images can also be sent to PACS server. Moreover, the patient information and database can be managed through the monitor cart
- Medical monitor: It displays the images by the monitor through visualizing the image signals. It displays live image on the left, and reference image on the right.

### 3) Accessories

- Foot switch: It is used for fluoroscopy and can save images.
- Hand switch: It is used in both radiographic and fluoroscopic modes. It controls X-ray generation.

## 6. Indication for use

XPlus 35 Series (XPLUS 35, XPLUS 35FD) are mobile digital C-arms designed to provide fluoroscopic and radiographic images of the patient during diagnostic, surgical and interventional procedures.

Examples of clinical application may include endoscopy, orthopedic, neurologic, 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.

Comparison of the subject device to the predicate device.

Descriptive Information	Subject Device	Predicate Device	Reference Device	Note
Manufacturer	GEMSS HEALTHCARE CO., LTD.	GENORAY Co., Ltd.	SG HealthCare Co. Ltd.	-
Device Name	XPLUS 35, XPLUS 35 FD	ZEN-2090 Pro	Garion	
510(k) number	K233200	K091918	K222080	-
Regulatory Number	21CFR 892.1650	21 CFR 892.1650	21 CFR 892.1650	Same
Product Code	OWB, JAA, OXO	OWB, JAA, OXO	OWB	Same
Regulatory Class	2	2	2	Same
Indications for Use	XPLUS 35 series (XPLUS 35, XPLUS 35FD) are mobile digital C-arms designed to provide fluoroscopic and radiographic images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include orthopedic, neurologic, vascular, cardiac, angiography, endoscopy, urologic, 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.	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 location, 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.	The Garion is intended to be used and operated by: adequately trained, qualified and authorized health care professionals who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device. The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients, except neonates (birth to one month), within the limits of the device. The device is to be used in healthcare facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures.	Similar

Radiographic Mode	kV range	40 to 110 kV	40 to 110 kV	40 to 125 kV	Same
	mA Range	30 to 45 mA	20 mA	0.3~ 32 mA	Similar
	mAs Range	1.0 to 200 mAs	0.4 to 100 mAs	0.2 ~ 100 mAs	Similar
Fluoroscopic Mode	kV range	40 to 110 kV	40 to 110 kV	40 to 110 kV	Same
	mA range	0.2 to 8 mA 10 mA (Boost Mode)	0.2 to 6 mA 10 mA (Boost mode)	0.3 ~ 6.3 mA	Similar
	Pulse Fluoro	Yes	Yes	Yes	Same
C-arm	Range of C-arm Rail Rotation	I.I Type: 135 ° (90 ° / 45 °) FPD Type: 165° (120° / 45°)	120 ° (90 ° / 30 °)	150 °	Similar
	Range of the Horizontal C-arm Movement	200 mm	200 mm	200 mm	Same
	Range of the Vertical C-arm Movement	500 mm	400 mm	400 mm	Similar
	Range of Swing-arm Movement	± 12.5 °	± 12.5 °	± 15 °	Same
	Range of Stay-arm Rotation	225 °	180 °	180 °	Similar
Image Receptor	Image Intensifier	E5830SD-P4A (Manufactured by TOSHIBA) 9" / 6" / 4.5"	E5830SD-P4A (Manufactured by TOSHIBA) 9" / 6" / 4.5"	-	Same
	Flat Panel Detector	Mercu 0909F (Manufactured by IRay) 9"	-	Mercu 0909F (Manufactured by IRay) 9"	
	Pixel Pitch	205µm	N/A	205µm	Same
	DQE @ 0 lp/mm	77% at 0lp/mm	65% at 0lp/mm	77% at 0lp/mm	Same
	MTF @ 1lp/mm	61%	N/A	61%	Same
	Frame rates (fps values)	N/A for I.I. Up to 60fps for FPD	N/A	Up to 60fps	Same
Collimators		Iris and Leaf	Iris and Leaf	Motor control/rotation	Same
Laser Guide		Yes	Yes	Yes	Same
	Model	DF-151SBR (Manufactured by Canon)	DF-151SBR (Manufactured by Canon)	Rotating Anode (200kHU)	Same

X-ray Tube	Anode Type	Stationary Anode	Stationary Anode	Rotating anode	Same
	Focal size	0.5/1.5 mm	0.5/1.5 mm	0.3/0.6 mm	Same

XPLUS 35 Series (XPLUS 35, XPLUS 35FD) is substantially equivalent to the predicate device ZEN-2090 Pro (K091918) and Garion (K222080) These devices are very similar in the intended use, the design principle, the performance and the applicable standards. Some characteristics, for example, different X-ray generators, the appearance, and the user interfaces are different. The X-ray generator capacity of the subject device has higher maximum power output compared with the predicate devices. The subject device utilized both solid state X-ray imager (FPD) and image intensifier which are the same as the predicate devices. All detectors used for the subject devices have been already cleared by FDA and do not raise new concerns for safety and effectiveness. However, these small and minor differences do not raise any new questions of safety and effectiveness.

## 8. Safety, EMC and Performance data comparison to Predicate

- IEC60601-1 (ed3.1, 2012), Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (Recognition No: 19-4)
- IEC60601-1-2: 2014, Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests (Recognition No: 19-8)
- IEC60601-1-3 (ed 2.1, 2013), Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment (Recognition No: 12-269)
- IEC60601-2-28 (ed 3, 2017) Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis (Recognition No: 12-309)
- IEC60601-2-43 (ed 2.2, 2019) Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures (Recognition No: 12-329)

In addition, the device complies with the FDA Radiation Safety Performance Standard Performance Standard for Diagnostic X-Ray Systems and Their Major Components (21CFR 1020.30, 1020.31, 1020.32); Small Entity Compliance Guide. In addition, labeling was developed and information provided in accordance with this FDA Guidance Document: Pediatric Information for X-ray Imaging Device Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff. Labeling also includes reference to the Image Gently website (<http://www.imagegently.org/>). Also we observed the recommendations contained in the FDA Guidance Document: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff.

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" to ensure substantial equivalence.

Results demonstrated that all executed verification tests were passed.

Non-clinical validation testing has been performed to validate that XPLUS 35 Series (XPLUS 35, XPLUS 35FD) 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 XPLUS 35 Series (XPLUS 35, XPLUS 35FD) is safe and effective as predicate device, and has no new indication for use. Therefore, XPLUS 35 Series (XPLUS 35, XPLUS 35FD) is substantially equivalent to predicate device.