November 6, 2025

Hefei Chimed Intelligent Machine Co., Ltd
% Garen Liu
Consulting Consultant
Grzan medical technology (Shenzhen) Co., LTD.
Room 103-108, 1st Floor, Block B, Building 2, Bangkai
Science and Technology Park, Guanguang Road, Guangming Distr
SHENZHEN, 518107
CHINA

Re: K251004
Trade/Device Name: Dual-Mode Mobile C-Arm (Geelin500A, Geelin500M)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OXO, JAA
Dated: September 18, 2025
Received: September 30, 2025

Dear Garen Liu:

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 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 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 systems (QS) regulation (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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic 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)*
K251004

Device Name
Dual-Mode Mobile C-Arm (Geelin500A, Geelin500M)

Indications for Use *(Describe)*
The Geelin500A/Geelin500M is a mobile digital X-ray C-Arm diagnostic system, which Is Intended to generate X-ray fluoroscopic image of a patient. The application includes: real-time positioning and monitoring operations in trauma surgery, orthopedics, spine surgery, and chest surgery, it is not intended to be used in interventional procedures. The Geelin500A/Geelin500M permits a qualified doctor or technologist to take a range of diagnostic exposures of spinal column, chest, abdomen, extremities, and other body parts on the patients at the age of at least eighteen.

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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013_510k Summary

This 510(k) Summary is being submitted in accordance with requirements of T itle 21, CFR Section 807.92.

The assigned 510(k) Number: K251004
Date of Preparation: 28/10/2025

1. Information of Submitter and correspondent

Submitter's information

Submitter Name: Hefei Chimed Intelligent Machine Co., Ltd
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Contact Person (including Title): Li min (Manager)
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Correspondent's information

GRZAN Medical Technology (SZ) Co., Ltd.
Address: Room 103-108, 1st Floor, Block B, Building 2, Bangkai Science and Technology Park, Guanguang Road, Guangming District, Shenzhen, 518107, China.
Contact Person: Garen Liu
E-mail: garen@grzan.cn

2. Device Identification

- Type of 510(k) submission: Traditional
- Common Name: Image-intensified fluoroscopic x-ray system, mobile; system, x-ray, fluoroscopic, image-intensified
- Trade Name: Dual-Mode Mobile C-Arm (Geelin500A, Geelin500M)
- Classification Name: Image-intensified fluoroscopic x-ray system
- Regulation Medical Specialty: Radiology
- Review Panel: Radiology
- Product Code:OXO, JAA
- Regulation Number: 21 CFR 892.1650
- Device Classification: 2

3. Discussion of Non-clinical test and clinical test for Determination of Substantial Equivalence are as follows:

3.1 Non-clinical testing

A series of safety and performance tests were conducted on the subject device.

- Performance Test
- Electrical safety

Non-clinical performance testing was conducted to evaluate electrical safety, mechanical stability, radiation safety, and imaging performance of the Dual-Mode Mobile C-Arm (Models Geelin 500A/500M). The device achieved consistent and accurate imaging with high spatial and contrast resolution, stable radiation output, and compliance with dose display accuracy requirements. Comparative phantom evaluations demonstrated that the imaging quality of the subject device is comparable to or better than the predicate device and reference device.

All the test results demonstrate Dual-Mode Mobile C-Arm meets the requirements of its predefined acceptance criteria and intended use, and it is substantially equivalent to the predicate device.

4. Indications for Use

The Geelin500A/Geelin500M is a mobile digital X-ray C-Arm diagnostic system, which Is Intended to generate X-ray fluoroscopic image of a patient. The application includes: real-time positioning and monitoring operations in trauma surgery, orthopedics, spine surgery, and chest surgery, it is not intended to be used in interventional procedures. The Geelin500A/Geelin500M permits a qualified doctor or technologist to take a range of diagnostic exposures of spinal column, chest, abdomen, extremities, and other body parts on the patients at the age of at least eighteen.

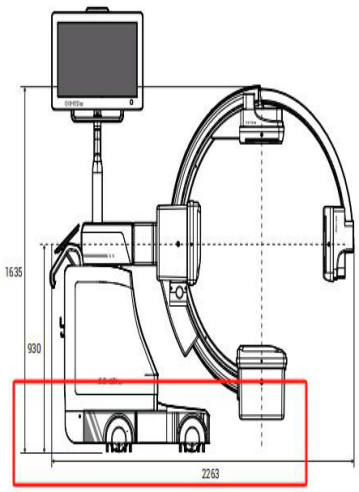
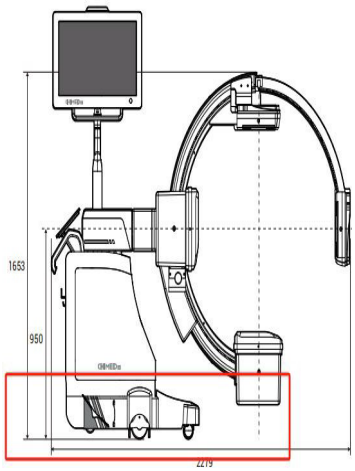
5. Predicate Device and Reference Device Information

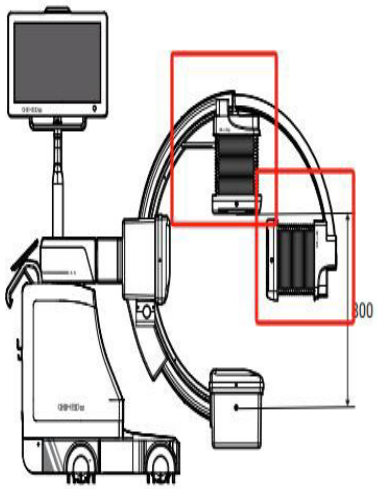
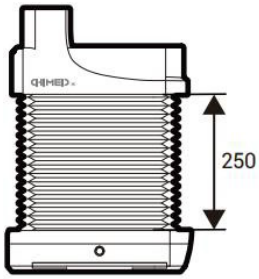
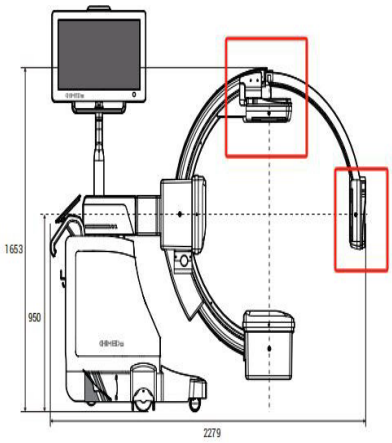
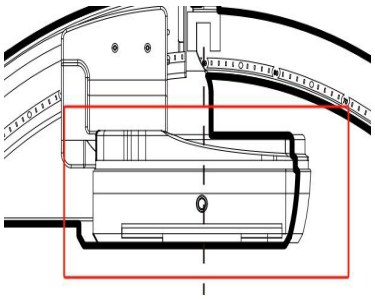
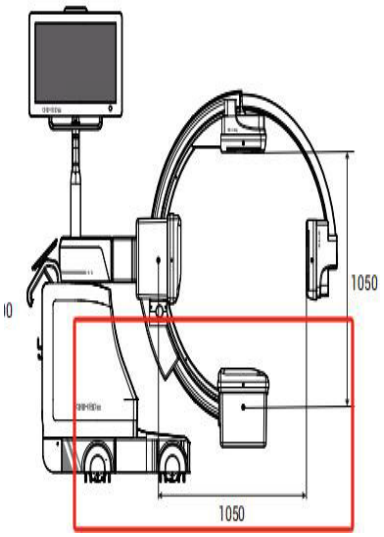
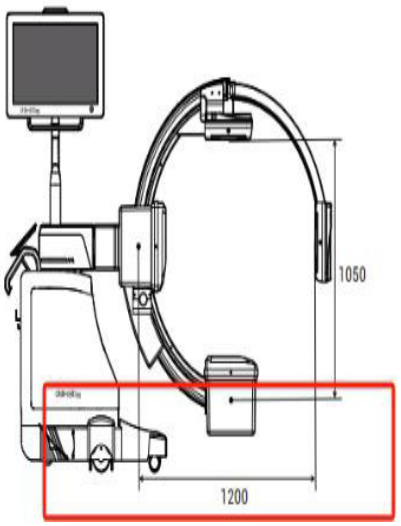
Predicate device Information	
Manufacturer	Beijing East Whale Imaging Technology Co., Ltd.
Device Name	DigiArc 100AU
510(k) Number	K151280
Product Code	OXO, JAA
Regulation Number	21 CFR 892.1650
Regulation Class	2
Reference Device Information	
Manufacturer	GE Hualun Medical Systems Co., Ltd.
Device Name	OEC OneTM
510(k) Number	K172700
Product Code	OWB, OXO, JAA
Regulation Number	21 CFR 892.1650
Regulation Class	2
Reference Device Information	
Manufacturer	Dornier MedTech America
Device Name	Trident Mobile Fluoroscopy System
510(k) Number	K233380
Product Code	JAA
Regulation Number	21 CFR 892.1650
Regulation Class	2

6. Device Description

The Dual-Mode Mobile C-Arm is divided into two models, and the differences between the models are shown in the table below:

Item	Geelin500A	Geelin500M	Note
Structural component	The product comprises X-ray generator, X-ray imaging device, C-Arm retractable rack, accessories, and software. The X-ray generator consists of monoblock head ,inverter, and	The product comprises X-ray generator, X-ray imaging device, C-Arm retractable rack, accessories, and software. The X-ray generator consists of monoblock head ,inverter, and	Same

Item	Geelin500A	Geelin500M	Note
	collimator. The X-ray imaging device includes digital image detector, image display, Touch Screen, and industrial computer. Accessories consist of battery, movement control handle, exposure foot switch, and laser. Software: Digital image processing software CMXPS-500, software release version V1.0.0.	collimator. The X-ray imaging device includes digital image detector, image display, Touch Screen, and industrial computer. Accessories consist of battery, movement control handle, exposure foot switch, and laser. Software: Digital image processing software CMXPS-500, software release version V1.0.0.	
Base plate			Different The chassis of the Geelin500M is equipped with swivel casters and requires manual pushing to move the equipment. The chassis of the Geelin500A is equipped with an electric motor, allowing movement of the equipment using the movement control handle..
SID	Variable（range:0-250mm)	Invariable	Different This feature is only available for Geelin500A. Geelin500M is a

Item	Geelin500A	Geelin500M	Note
	 	 	fixed Flat panel.
The distance from the X-ray tube focus to the image intensifier (lateral view)			Different The C-arm is equipped with a retractable digital image detector mechanism (only forGeelin500A), allowing for a variable source-to-image distance (SlD) from the tube focus to the detector plane. Distance (SlD) size from X-ray tube

Item	Geelin500A	Geelin500M	Note
			focus to digital image detector: Geelin500A: AP/LAT 1050 mm, variable (range 0-250mm) Geelin500M: AP 1050mm /LAT 1200mm, Invariable.

The Dual-Mode Mobile C-Arm is an X-ray device with dual-plane (A-vertical direction and B-horizontal direction) imaging function. Its main components are configured as follows:

1. Two E-40R HF/IMD XR05 combined X-ray generators (40kHz, using rotating anode X-ray tubes, suitable for fluoroscopy and digital radiography) produced by IMD CHINA CO.,LTD. Small focus: 0.3mm, nominal anode input power: 0.6kW; Large focus: 0.6mm, nominal anode input power: 5kW.

2. Two E-9040-5HF inverters produced by IMD CHINA CO.,LTD.

3. Two PaxScan2121DXV flat panel detectors produced by Varian Medical Systems.

4. The C-arm installs the two sets of X-ray systems on a 3/4 circular arc arm on the mechanical structure, and the ray directions of the two sets of systems are perpendicular to each other, showing an orthogonal relationship.

5. The ray control system of C-arm is composed of single chip microcomputer and configuration touch screen. The signals from the combined X-ray generator and inverter are converted into signals that can be received and processed by the single chip microcomputer through the exposure control board. At the same time, the AD\DA module

of the microcontroller provides filament preheating signals and kV setting signals for the ray generator and the inverter, and receives feedback signals from the inverter and the filament board.

6. The exposure program is controlled by the relevant program in the microcontroller. After stepping on the foot brake exposure pedal, the foot brake signal will enter the single-chip microcomputer program, and the single-chip microcomputer will determine whether the ray system (flat panel detector state, inverter state and filament state, etc.) is abnormal (error or warning) in real time. Under the normal condition of the system and the inverter without abnormality, the single-chip microcomputer will continue to delay 0.8 seconds to give the exposure command signal to the inverter. After receiving the exposure command signal, the inverter immediately executes the exposure command and excites the X-ray generator to release X-rays. At the same time, the inverter will monitor the kV feedback signal in real time. When the feedback signal is abnormal or the inverter is abnormal, the inverter will immediately transmit the signal to the single chip microcomputer, and the relevant error information will be realized on the touch screen, and the exposure command will be immediately forced to end. The filament board will also monitor the filament status in real time. When the filament board is abnormal or the filament current preheating is abnormal, the filament board will immediately transmit the signal to the microcontroller, and the relevant error information will be realized on the touch screen, and the exposure will be forced to end immediately.

7. The image generated by exposure is transmitted to the image processing workstation through the flat panel detector, and the workstation displays the image on the display screen after proper image processing.

7. Performance Test Summary

The Dual-Mode Mobile C-Arm was tested in accordance to the FDA recognized consensus standards listed below:

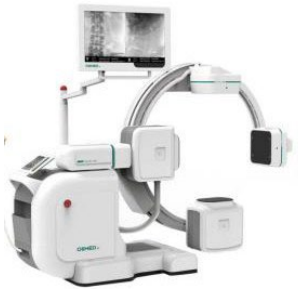
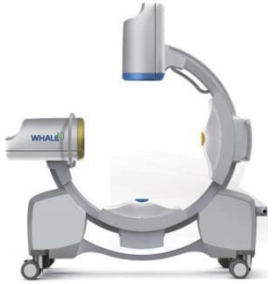
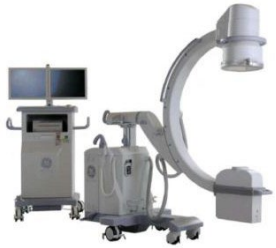
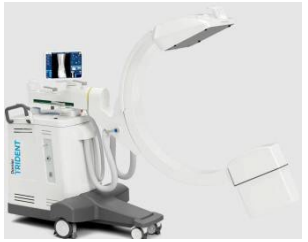
These non-clinical tests were conducted on finished representative product and using the methods outlined in these standards. This performance testing confirmed that the Dual-Mode Mobile C-Arm contains all of the applicable requirements of the following standards:

Test Type		**Outcome**
Electrical safety	IEC 60601-1 Edition 3.2	Conforms
EMC	IEC 60601-1-2 Edition 4.1 IEC TS60601-4-2 Edition 1.0	Conforms
Safety of Device	IEC 60601-1-3 Edition 2.2 IEC 60601-2-28 Edition 3.0 IEC 60601-2-54 Edition 2.0 IEC 60825-1 Edition 2.0	Conforms
Physical properties	Manufacturer's product technical requirements	Conforms
Image Comparative Testing	Comparative images using the Dual-Mode Mobile C-Arm and the DigiArc 100AU predicate device，OEC One Reference Device were taken to reflect usage conditions of the device. Images taken using phantom were reviewed by a qualified radiographer, and they were found to be clinically acceptable based on a comparison of devices.	Conforms
Physical property	To verify that C-arm, Image Receptor, X-ray Tube, Performance of imaging, Safety of radiation etc. meet the requirements of final product inspection standards through physical performance testing.	Conforms
Software Verification	The software has been documented for an Basic Documentation Level per FDA’s Guidance Document“Guidance for the Content of Premarket Submissions for Device Software Functions” issued on June 14, 2023.	Conforms
Cybersecurity Verification	According to the FDA's Guidance Document "Cybersecurity in Medical Devices: Quality System Considerations	Conforms

	and Content of Premarket Submissions" issued on September 27, 2023. The cybersecurity of the equipment was evaluated and verified	

Successful bench and image testing results demonstrate substantial equivalence to the predicate device. The results of the non-clinical performance standard testing further supports the safe and effective use of the Dual-Mode Mobile C-Arm.

8. Substantial Equivalence information

Descriptive Information	**Subject Device**	**Predicate Device (K151280)**	**Reference Device (K172700)**	**Reference Device (K233380)**	**Comments**
Manufacturer	Hefei Chimed lntelligent Machine co.,Ltd	Beijing East Whale Imaging Technology Co., Ltd.	GE Hualun Medical Systems Co., Ltd.	Dornier MedTech America	/
Device Name/Model	Geelin500A/Geelin500M	DigiArc 100AU	OEC One™	Trident Mobile Fluoroscopy System	/
Class of Device	Class 2	Class 2	Class 2	Class 2	Same
Product code	OXO, JAA	OXO, JAA	OWB, OXO, JAA	JAA	Same
Product picture					/
Indications for Use	The Geelin500A/Geelin500M	The DigiArc 100AU/ DigiArc 100AU+ is a	The OEC One mobile C-arm system is designed to provide	The Trident Mobile Fluoroscopy System is	Same, the indications for use

	is a mobile digital X-ray C-Arm diagnostic system, which Is Intended to generate X-ray fluoroscopic image of a patient. The application includes: real-time positioning and monitoring operations in trauma surgery, orthopedics, spine surgery, and chest surgery, it is not intended to be used in interventional procedures. The Geelin500A/Geelin500M permits a qualified doctor or technologist to take a range of diagnostic exposures of spinal column, chest, abdomen,	mobile digital X-ray G-Arm diagnostic system, which is intended to generate X-ray fluoroscopic image of a patient. The application includes: real-time positioning and monitoring operations in trauma surgery, orthopedics, spine surgery, and chest surgery, it is not intended to be used in interventional procedures. The DigiArc 100AU/ DigiArc 100AU+ permits a qualified doctor or technologist to take a range of diagnostic exposures of spinal column, chest, abdomen, extremities, and other	fluoroscopic and digital spot/film images of adult andpediatric patient populations during diagnostic, interventional, and surgical procedures. Examples of a clinical applicationmay include: orthopedic, gastrointestinal, endoscopic, urologic, neurologic, critical care, and emergency procedures.	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.	of the subject device are the same as those of the predicate device(K151280).

		extremities, and other body parts on the patients at the age of at least eighteen.	body parts on the patients at the age of at least eighteen.			
C-arm	SID	800 ~ 1050mm ±5%	950 ~1250 mm ±10 mm	1000 mm	1041 mm	Different ,the SID of the Subject Device and the Predicate Device (K151280) are very close, and subtle differences do not result in poor imaging quality or a larger radiation dose. the range of motion of the C-arm of the Subject Device is basically the same as that of the Predicate Device
	C-arm guide rail rotation range	-40° ~ +52°	±34°	120°	/	
	C-arm lateral rotation range	±20°	No	±205°	/	
	C-arm swing range	No	No	±12.5°	/	
	Image Receptor adjustment range:	250mm	300 mm±5 mm	No	/	
	Vertical lifting	300mm	300mm±10mm	445 mm	/	

						(K151280).
Nominal electric power		1.5kW（100kV，15mA，1.06s）	1.5 kW (100 kV, 15 mA, 1 s)	2.0kw (100kV, 20mA, 0.1s)	20 kW	Same
Radiogra phic Mode		1. Digital radiography mode 2. Continuous fluoroscopy mode 3. Pulse fluoroscopy mode 4. Pulse fluoroscopy (high dose) mode 5. Pulse fluoroscopy (low dose) mode 6. Spot-Film digital radiography mode	1. Automatic continuous perspective mode 2. Manual continuous perspective mode 3. Automatic pulse perspective mode 4. Manual pulse fluoroscopy mode 5. Enhanced mode (automatic continuous perspective mode) 6. Half dose mode (1/2 Automatic continuous perspective mode) 7.Half dose mode (1/2	1. Normal perspective mode 2. Enhanced perspective mode 3. Pulse perspective mode 4. Low dose fluoroscopy mode 5. Spot-Film digital radiography mode 6. Shooting mode	1. Radiographic 2. Fluorographic	Different, the Predicate Device (K151280) and Reference Device (K172700) cover the operating mode of the Subject Device

			Automatic pulse perspective mode)			
Image Receptor	Model	PaxScan 2121 DXV	TH 9428 HP2	23XZ4ST/BS, TH9438HXH249VR19 ST	PaxScan 3030 DX OR PaxScan 2121 DXV	Same, Same, the Image Receptor model of the Subject Device is the same as the Reference Device (K233380).
	Field of Irradiation	21cm×21cm	21.5cm	Normal mode: 9”（23 cm) Mag1 mode: 6”（15cm) Mag1 mode: 4.5”(11cm)	PaxScan2121 DXV: 209.9 x 209.9mm	
	DQE	80% at 0 lp/mm 65% at 1 lp/mm 40% at 2 lp/mm	65% at 0 lp/mm	65% at 0 lp/mm	/	
Resolution of image		1K×1K	1K×1K	1K×1K	PaxScan2121 DXV: 1004 x 1004	Same
Collimators		When SID is adjusted, the system detects the change value of SID and adjusts the	Unknown	X-ray beams can be adjusted for beam limiting by Collimators adjusting parallel	Model: RALCO R650/027/QDASM	Same

		opening size of Collimators in real time according to the change value (Geelin500A Only). It is also possible to manually control the opening and closing of Collimators. The beam limiter is open and closed at the same time for left and right, and open and close at the same time for up and down		gratings or circular apertures.		
X-ray Tube	Anode Type	Rotating Anode	Stationary Anode	Stationary Anode	Rotating anode	Same, the anode type of the Subject Device is the same as the Reference Device (K233380)
	Minimum inherent filtration	2 mm Al at 80 kV Additional filtration: 2mm Al	2.0 mmAl at 80 kV	0.55mm Al at 50kV	Unknown	Same

	Focal size	Small focus 0.3mm, Large focus 0.6mm	Small focus 0.6mm, Large focus 1.5mm	Small focus 0.6×1.4mm, Large focus 1.4mm	0.3 mm and 0.6 mm	Same, the focal size of the Subject Device is the same as the Reference Device (K233380)
	Leakage ray	At a distance of 1m from the focal point, the average dose rate in any area of 100 cm^2 (the linear length is not more than 20cm) is less than 1.0 mgy/h.	At a distance of 1m from the focal point, the average dose rate in any area of 100 cm^2 (the linear length is not more than 20cm) is less than 1.0 mgy/h.	At a distance of 1m from the focal point, the average dose rate in any area of 100 cm^2 (the linear length is not more than 20cm) is less than 1.0 mgy/h.	/	Same
Focal spot to skin distance		≥20 cm	20 cm	30 cm	/	Same
Inverter	Working frequency:	20kHz	20kHz	/	/	Same
	Maximum peak voltage	350VAC	350 VAC	/	/	Same
	Maximum peak current	130A	130A	/	/	Same

Permanent filtration		4.0mmAl	/	3.35 mm Al	/	Different, the Subject Device has a larger Permanent filtration than the Reference Device(K172700), which reduces radiation better
Performance of imaging	Spatial resolution	2.5 lp/mm	≥ 2.0 lp/mm	4.4 lp/mm	PaxScan 2121 DXV: 2.43 lp/mm @ 15 fps ， 1.22 lp/mm @ 30 fps.	Different, the Spatial resolution of the Subject Device(K151280) is larger than that of the Predicate Device(K151280), which can present clearer image details.
	low-contrast resolution	Perspective ≤ 5.6%. Digital radiography ≤ 4%.	<2%	4%	/	Different, There are slight differences under perspective

						type, and the digital radiography type is the same as Reference Device(K172700).
	Discernible Dynamic Wedge Number	Perspective ≤14. Digital radiography ≤16.	≥10	16	/	Different, The Discernible Dynamic Wedge Number of the Subject Device is overwritten by the Predicate Device(K151280) and Reference Device(K172700)
	Pulse fluoroscopy frame rate adjustment range	8, 12, 16 FPS	4、8、12、15 FPS	1、2、4、8 FPS	/	Different, the Pulse fluoroscopy frame rate adjustment range of the Subject Device is overwritten by the

						Predicate Device(K151280) and Reference Device(K172700)
	Imaging time	Perspective ≤1s. Digital radiography ≤5s.	Perspective ≤1s. Digital radiography ≤5s.	Perspective ≤1s. Digital radiography ≤5s.	/	Same
	Image stabilization time	At continuous and highest pulse perspective frame rates, no more than 2s.	At continuous and highest pulse perspective frame rates, no more than 2s.	At continuous and highest pulse perspective frame rates, no more than 2s.	/	Same
	Fluoroscopy recovery time	≤ 5 min.	≤ 5 min.	≤ 5 min.	/	Same
	Artifacts	Imaging was free of artifacts.	Imaging was free of artifacts.	Imaging was free of artifacts.	/	Same
Safety of radiation	Display error of irradiation dose	≤ ±35%	≤ ±35%	≤ ±35%	/	Same
	Radiation dose on the incident surface of the	Perspective ≤0.714uGy/s. Digital radiography	≤ 5.0 μGy/s	≤ 5.0 μGy/s	/	Different, the Radiation dose of the Subject Device

	Image Receptor	≤2.38uGy/FPS.				is smaller and safer.
	Air kerma rate	≤ 88mGy/min.	≤ 88mGy/min.	≤ 88mGy/min.	/	Same
		Device is working in the state of high dose, the system has a continuous alarm indicating state, which should not exceed 176mGy/min.	Device is working in the state of high dose, the system has a continuous alarm indicating state, which should not exceed 176mGy/min.	Device is working in the state of high dose, the system has a continuous alarm indicating state, which should not exceed 176mGy/min.	/	Same
Noise		The noise produced by the operation in the no-load state should not exceed 70dB (A) (excluding non-sustained periodic noise within 3s).	Device is working in the state of high dose, the system has a continuous alarm indicating state, which should not exceed 176mGy/min.	Device is working in the state of high dose, the system has a continuous alarm indicating state, which should not exceed 176mGy/min.	/	Same
Foot pedal switch		Yes	Yes	Yes	Yes	Same

The Geelin500A/Geelin500M is basically equivalent to the Predicate Device (K151280)/Reference Device (K172700), and these devices are very similar in terms of intended use, design rationale, performance, and applicable standards. Some features, such as different C-arm adjustment range, X-ray Tube, Image Receptor appearance and user interface are different.

The C-arm of the Subject Device has a larger range of adjustment and is more convenient to operate. The operating mode of the Device is generally the same as that of the Predicate Device and the Reference Device, with minor differences in imaging performance and radiation safety, but all meet the relevant standard standards.

Subject Device and Predicate Device (151380) use different Image receptors, but it is the same as the Image receptors of Reference Device (K233380), and they all use PaxScan2121 DXV.

However, these differences do not raise any new questions about safety and efficacy.

9. Date of the summary prepared: October 28, 2025