December 9, 2024

Shenzhen Browiner Tech Co., Ltd
% Long Yang
COO
Shenzhen Hlongmed Biotech Company
16th floor, Tianming Technology Building, No.8 Wushitou Road
Songpingshan Community, Xili Street, Nanshan District
Shenzhen, GD 518052
CHINA

Re: K240841
Trade/Device Name: Digital Radiography System (ManntiX B, ManntiX K)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL, MQB, LLZ
Dated: November 5, 2024
Received: November 5, 2024

Dear Long Yang:

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.

Submission Number *(if known)*

K240841

Device Name

Digital Radiography System (ManntiX B, ManntiX K)

Indications for Use *(Describe)*

Intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the desired parts of patient's anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities).
This device is not intended for mammography.

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.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(K) number is: K240841

1. Submitter

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3. Date Prepared: December 5, 2024

4. Proposed Device Information

Trade name: Digital Radiography System (ManntiX B, ManntiX K)

Regulation Name: Mobile X-Ray System

Classification name: System, X-Ray, Mobile

Review Panel: Radiology

Product Code:Primary Product Code: IZL; Secondary Product Code: MQB, LLZ

Regulation Class: II

Regulation Number: 21 CFR 892.1720

5. Predicate Device Information

Manufacturer	**Proprietary /Trade Name**	**510(K) Number**
Shantou Institute of Ultrasonic Instruments Co., Ltd. (SIUI)	SR-2300 Portable DR Imaging System SR-2300S Portable DR Imaging System	K202353

Device Name: SR-2300 Portable DR Imaging System, SR-2300S Portable DR Imaging System

Regulation Name: Mobile X-Ray System

Classification name: System, X-Ray, Mobile

Review Panel: Radiology

Product Code:Primary Product Code: IZL; Secondary Product Code: MQB, LLZ

Regulation Class: II

Regulation Number: 21 CFR 892.1720

6. Device Description

This Digital Radiography System (ManntiX B, ManntiX K) is a portable digital device developed, designed and manufactured by Shenzhen Browiner Tech Co., Ltd. A detailed comparison table with an equivalent device are in 510(k) summary. The device consists of the following major components: portable X-ray Assembly, X-ray Protective Device, Mobile Stand, Digital Detector, image processing system. The difference between ManntiX B and ManntiX K are as below.

Model	ManntiX B	ManntiX K
Portable X-ray Assembly (including collimator and tube)	PX10	PX10 Pro
X-ray Protective Device (optional)	BA-01	
Mobile Stand	MS-05P	MS-10P
Digital Detector (optional)	CareView 1500Cwe	
	Mars1717X	
	Luna 1012X	
Image Processing System (optional)	MOC（V03）	
Image Acquisition Workstation (optional)	BWS-10	

Note:

1. ManntiX B and ManntiX K are delivered with one of CareView1500Cwe, Mars1717X and Luna 1012X, or two of them, or three of them.
2. A computer system, necessary for image viewing and manipulation, is not part of the device.

The major components of Digital Radiography System include: portable x-ray assembly, x-ray protective device, mobile stand, digital detector, image processing system, image acquisition workstation.

Portable X-ray assembly including collimator and tube, produces X-rays at the clinically required dose; X-ray protective device is used to protect the human body during diagnostic radiography; mobile stand is used to support or hang X-ray source components; digital detector receives X-ray signals and converts them into visible light, which is converted into electrical signals by photoelectric elements and then converted into digital signals by analog-to-digital conversion before being transmitted to the computer; image processing system has multiple functions, including new patient registration, image acquisition and processing, data transmitting, etc; image acquisition workstation is used in addition to the image processing system to adjust exposure parameters, check the status of the entire machine, and view logs.

7. Intended use

Intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the desired parts of patient's anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities).

This device is not intended for mammography and pediatric patients.

8. Comparison to Predicate Device

The Digital Radiography System have the similar intended use, similar technological characteristics as the following predicate device. Subject Device is substantially equivalent in its technologies and functionality to the SR-2300 Portable DR Imaging System/SR-2300S Portable DR Imaging System manufactured by Shantou Institute of Ultrasonic Instruments Co., Ltd. (SIUI) that is already cleared under premarketed notification number K202353.

The details of the technological characteristics of the subject device ManntiX versus the predicate SR-2300 are as stated below:

Item		Proposed Device	Predicate Device
Device Name		Digital Radiography System	SR-2300 Portable DR Imaging System SR-2300S Portable DR Imaging System
Model		ManntiX B ManntiX K	SR-2300 SR-2300S
510(k) number		K240841	K202353
Submitter		Shenzhen Browiner Tech Co., Ltd	Shantou Institute of Ultrasonic Instruments Co., Ltd. (SIUI)
Intended use		Intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the desired parts of patient's anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities). This device is not intended for mammography and pediatric patients.	Intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the desired parts of patient's anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities). This device is not intended for mammography.
Indications for use		Intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the desired parts of patient's anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities). This device is not intended for mammography and pediatric patients.	Intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the desired parts of patient's anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities). This device is not intended for mammography.
Basic Generator Characteristics	Peak generator	Maximum Power kW: 10 kW (100 mA, 100 kV) Nominal Power kW: 8 kW (80 mA , 100 kV, 100 ms)	5W
	Tube current	5-160 mA, ±20%. Contain the following mA slot: 5, 6, 7, 8, 10, 11, 12.5, 14, 16, 18, 20,	10-100mA

Item		Proposed Device	Predicate Device
		22, 25, 28, 32, 36, 40, 45, 50, 56, 63, 71, 80, 90, 100, 110, 125, 140, 160	
	Tube voltage adjustable range	40-125kV, step value 1kV	40-125kV, step value 1kV
	mAs range	AC: from 0.1 mAs to 360 mAs, ±(10 % + 0.2 mAs). Contain the following mAs slot: 0.1, 0.11, 0.125, 0.14, 0.16, 0.18, 0.2, 0.22, 0.25, 0.28, 0.32, 0.36, 0.4, 0.45, 0.5, 0.56, 0.63, 0.71, 0.8, 0.9, 1.0, 1.1, 1.25, 1.4, 1.6, 1.8, 2.0, 2.2, 2.5, 2.8, 3.2, 3.6, 4.0, 4.5, 5.0, 5.6, 6.3, 7.1, 8.0, 9.0, 10, 11, 12.5, 14, 16, 18, 20, 22, 25, 28, 32, 36, 40, 45, 50, 56, 63, 71, 80, 90, 100, 110, 125, 140, 160, 180, 200, 220, 250, 280, 320, 360 DC: from 0.1 mAs to 80 mAs,±（10 % + 0.2 mAs). Contain the following mAs slot: 0.1, 0.11, 0.125, 0.14, 0.16, 0.18, 0.2, 0.22, 0.25, 0.28, 0.32, 0.36, 0.4, 0.45, 0.5, 0.56, 0.63, 0.71, 0.8, 0.9, 1.0, 1.1, 1.25, 1.4, 1.6, 1.8, 2.0, 2.2, 2.5, 2.8, 3.2, 3.6, 4.0, 4.5, 5.0, 5.6, 6.3, 7.1, 8.0, 9.0, 10, 11, 12.5, 14, 16, 18, 20, 22, 25, 28, 32, 36, 40, 45, 50, 56, 63, 71, 80	0.4mAs-200mAs, with the range of: 0.40, 0.50, 0.63, 0.80, 1.00, 1.25, 1.6. ,2.0 ,2.5 ,3.2, 4.0, 5.0, 6.3, 8, 10, 12.5 ,16, 20, 25, 32, 40, 50, 63, 80, 100, 125, 160, 200
Collimator		Built in	Built in
X-ray Generator		One model, up to 125kVp	One model, up to 125kV
Operator console		Button Control or Touch Screen	Button Control or Touch Screen
Digital X-Ray Detectors		Mars1717X (K210314) CareView 1500Cwe (K201932)	SFD-1X

Item	Proposed Device	Predicate Device
	Luna 1012X (K221345)	
Panel Shape	Mars1717X: Rectangular Panel CareView 1500Cwe: Rectangular Panel Luna 1012X: Rectangular Panel	Rectangular Panel
Detector Size	Mars1717X: 17”X17” CareView 1500Cwe: 14”X17” Luna 1012X: 10”X12”	14"X17”
Pixel Pitch	Mars1717X: 100 µm CareView 1500Cwe: 140 µm Luna 1012X: 100 µm	150 µm
Materials Scintillator	TFT - -amorphous Silicon	TFT - -amorphous Silicon
DQE	**Mars1717X:** 51% at 1.0 lp/mm 36% at 2.0 lp/mm 25% at 3.0 lp/mm **CareView 1500Cwe:** 43% at 1.0 lp/mm 30% at 2.0 lp/mm 15% at 3.0 lp/mm **Luna 1012X:** 51% at 1.0 lp/mm 36% at 2.0 lp/mm 25% at 3.0 lp/mm	36% at 1.0 lp/mm 13% at 3.0 lp/mm
MTF	**Mars1717X:** 68% at 1.0 lp/mm 38% at 2.0 lp/mm 21% at 3.0 lp/mm **CareView 1500Cwe:** 60% at 1.0 lp/mm 32% at 2.0 lp/mm	38% at 2.0 lp/mm

Item	Proposed Device	Predicate Device
	17% at 3.0 lp/mm **Luna 1012X:** 68% at 1.0 lp/mm 38% at 2.0 lp/mm 21% at 3.0 lp/mm	
Communication Method	Wire Wireless IEEE 802.11a/b/g/n/ac(2.4GHz/5GHz) Security: WEP/WPA/WPA2	Wire Wireless IEEE 802.11a/b/g/n (2.4GHz/ 5GHz) Security: WEP/WPA/WPA2
Components that can communicate wirelessly	Digital Detectors	Digital X-Ray Detectors
Type of scintillator	Amorphous silicon	Amorphous silicon
Type of use	Removable detector	Removable detector
Effective imaging area	Mars1717X: 430 mm ×430 mm; CareView 1500Cwe: 430 mm × 358 mm; Luna 1012X: 315 mm ×250 mm. Not less than 95% of the nominal effective field of view	Not less than 95% of the nominal effective field of view(430mm × 350mm).
Spatial resolution	Mars1717X: ≥5.0 lp/mm CareView 1500Cwe: ≥3.6 lp/mm Luna 1012X: ≥5.0 lp/mm	Not less than 3.6 lp/mm, without the attenuator module.
Grayscale	16 bit	Up to 16 bit.
Acquisition pixel	Mars1717X: 4267×4267 CareView 1500Cwe: 3072×2560 Luna 1012X: 3152×2502	Not less than 2500×3052.
Imaging time	Mars1717X: No more than 12s. CareView 1500Cwe: No more than 10s. Luna 1012X: No more than 8s.	The fastest system imaging time is 8s.
Acquisition Software	MOC (V03)	PIE-5
Software function	Image viewing Image search Image storage	Image viewing Image search Image storage

Item	Proposed Device	Predicate Device
	Image annotation Image measurement Image processing Image stitch	Image annotation Image measurement Image processing Image stitch
DICOM 3.0 Compatibility	Yes	Yes
Photos		 Note: The portable stand is an optional component.
Power Source	AC Line or rechargeable batteries	AC Line or rechargeable batteries
Standard	IEC 60601-1 IEC60601-1-2 IEC60601-2-54 IEC60601-1-3 ISO 10993-1 IEC 62304 IEC 62366-1	IEC 60601-1 IEC60601-1-2 IEC60601-2-54 IEC60601-1-3 ISO 10993-1 IEC 62304 IEC 62366-1

9. Biocompatibility

The Digital Radiography System have been evaluated in accordance with Part 10993 of the International Standard Organization (ISO). Standard tests administered include:

• ISO 10993-1 Fifth edition 2018-08

Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

10. Summary of non-clinical performance Tests

• IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

• IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

• IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION

Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

• IEC 60601-2-54 Edition 1.2 2018-06 CONSOLIDATED VERSION

Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

• IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes

• IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION

Medical devices - Part 1: Application of usability engineering to medical devices

11. Substantial Equivalent Conclusions

Digital Radiography System has the similar intended use, similar technological characteristics as the predicate device. Moreover, non-clinical testing contained in this submission demonstrated that any difference in their technological characteristics does not raise any new issues of safety and effectiveness.

In conclusion, Digital Radiography System is substantial equivalent to the predicate device.