March 28, 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: K240284
Trade/Device Name: Digital Radiography System (MobileApex 60E, MobileApex 60F, MobileApex 60G, MobileApex 60H)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL, MQB
Dated: January 31, 2024
Received: February 1, 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.

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,

Gabriela M. Rodal -S

Digitally signed by Gabriela M. Rodal -S

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)*
K240284

Device Name
Digital Radiography System (MobileApex 60E, MobileApex 60F, MobileApex 60G, MobileApex 60H)

Indications for Use *(Describe)*

Intended for use by a qualified/trained doctor or technician on adult subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not 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.

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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: K240284
Date of Summary: March 27, 2024

1. Submitter

Shenzhen Browiner Tech Co., Ltd.

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2. Contact Person

2.1 Primary Contact Person

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3. Date Prepared: March 27, 2024

4. Proposed Device Information

Trade name: Digital Radiography System (MobileApex 60E, MobileApex 60F, MobileApex 60G, MobileApex 60H)

Model: MobileApex 60E, MobileApex 60F, MobileApex 60G, MobileApex 60H

Common name: Digital Radiography System

Classification name: Mobile X-ray System

Review Panel: Radiology

Product Code:Primary Product Code: IZL; Secondary Product Code: MQB Regulation

Class: II

Regulation Number: 21 CFR 892.1720

5. Predicate Device Information

Manufacturer	**Proprietary /Trade Name**	**510(K) Number**
Huestis Machine Corporation	MX40 Mobile Digital X-ray System	K181874

6. Device Description

The Digital Radiography System (MobileApex 60E, MobileApex 60F, MobileApex 60G, MobileApex 60H) is comprised of a High Voltage Generator with a maximum power output of 63kW, the Digital Radiography System (MobileApex 60E, MobileApex 60F, MobileApex 60G, MobileApex 60H) can meet different exposure needs for varying positions and body mass. With

the Digital Radiography System's (MobileApex 60E, MobileApex 60F, MobileApex 60G, MobileApex 60H) state-of-the-art design and powerful 63kW generator coupled with the Digital Detector (CareView 1500Cwe, CareView 750Cw, Mars1717X, Mars1417X, Luna 1012X) and Digital Radiography Operator Console, users can obtain clear images quickly and easily.

7. Intended use

Intended for use by a qualified/trained doctor or technician on adult subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.

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 MX40 Mobile Digital X-ray System manufactured by Huestis Machine Corporation that is already cleared under premarketed notification number K181874.

The details of the Technological Characteristics of Device as to Compare to the Predicate Device can are as below.

Item	**Proposed Device**	**Predicate Device**
Device Name	Digital Radiography System	MX40 Mobile Digital X-ray System
Model	MobileApex 60E MobileApex 60F MobileApex 60G MobileApex 60H	MX40
510(k) number	/	K181874
Submitter	Shenzhen Browiner Tech Co., Ltd	Huestis Machine Corporation
Intended use	Intended for use by a qualified/trained doctor or technician on adult subjects for	Intended for use by a qualified/trained doctor or technician on both adult and

Item	Proposed Device	Predicate Device
	taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.	pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.
General Information		
Modes of Operation	Manual	Manual
Classification Name	Mobile X-ray System	Mobile X-ray System
Classification Panel	Radiology	Radiology
Classification Regulation	21 CFR 892.§1720	21 CFR 892.§1720
Product Code	IZL	IZL
Subsequent Product Code	MQB	MQB
Medical Device Class	Class II	Class II
Performance Standard	21CFR1020.30	21CFR1020.30
Configuration	Mobile Battery or Line Operated	Mobile Battery or Line Operated
Power Source	Single Phase Line, 100V-240V~, ±10%	Single Phase Line Regulation from 100 - 240 Vac (+/-10%)
Electrical Safety and EMC	IEC 60601-1 and IEC 60601-1-2	IEC 60601-1 and IEC 60601-1-2
Standards (Other than Electrical and EMC)	WiFi 802.11a/b/g/n/ac and: FCC Rules and Regulations	Wi-Fi 802.11b/g and: FCC Rules and Regulations

Item	Proposed Device	Predicate Device
Generator		
Type	BWG-50-500D, manufactured by Shenzhen Browiner	Shenzhen Browiner
Generator Power Level	Nominal Power: 63 kW (630 mA, 100 kV, 100 ms) Maximum Power: 63 kW (630 mA, 100 kV)	50 KW
kV Range	40 - 150 kV, in 1 kV steps, ±10%	40 - 150 KV
mA Range	10 - 630 mA, ±20% Contain the following mA slot: 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, 400, 450, 500, 560, 630	10 - 630 mA
Exposure Time Range	1 - 10000 ms, ± (10%+1 ms) Contain the following time slot: 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, 400, 450, 500, 560, 630, 710, 800, 900, 1000, 1100, 1250, 1400, 1600, 1800, 2000, 2200, 2500, 2800, 3200, 3600, 4000, 4500, 5000, 5600, 6300, 7100, 8000, 9000, 10000	0.001 - 6.3 sec
mAs Range	0.1 - 630 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, 400, 450, 500,	0.1 - 320 mAs

Item	Proposed Device	Predicate Device
	560, 630	
X-Ray Tube		
Type	Siemens SDR-150/30/50 Canon E7252X	Toshiba E7843X
Material	Rhenium-Tungsten Molybdenum	Rhenium-Tungsten Molybdenum
Max Voltage	150 kV	150 kVp
Nominal Focal Spot	SDR-150/30/50: 0.6/1.0 E7252X: 0.6/1.2	0.6/1.2
Anode type	Rotating	Rotating
Nominal Anode Input Power	SDR-150/30/50: Small focus 43kW @ 180Hz Large Focus 81kW @ 180Hz E7252X: Small focus 27kW @ 180Hz Large Focus 75kW @ 180Hz	Large Focus 50kW @ 6Hz Small focus 22kW @ 60Hz
Imaging Panel		
Image acquisition panels (Both systems use already cleared digital panels)	**CareView 1500Cwe (K201932)** Pixels size: 140 µm 3072×2560 pixels **Mars1417X (K210316)** Pixels size: 100 µm 4300×3500 pixels **Mars1717X (K210314)** Pixels size: 100 µm 4267×4267 pixels **CareView 750Cw (K163019)** Pixels size: 120 µm 2560×2048 pixels **Luna 1012X (K221345)** Pixels size: 100 µm 3152×2502 pixels	**Varian 4336R** **PAXSCAN 4336W** Pixel Size 144 µm/3072 x 2560 pixels (previously cleared as part of K161459, 09/06/2016)

Item	Proposed Device	Predicate Device
System Software		
Image acquisition and control Software	MOC (V05)	ECOM Digital Radiography Operator Console (Acquisition Software and Graphical Interface-previously cleared as part of K130883 (04/18/13) and K143232 (01/30/15))
Operating System	Windows OS	Windows OS
Environment of use	Medical Facilities and/or Universities	Medical Facilities and/or Universities
Collimator		
Model	BRC-60, manufactured by Shenzhen Browiner	Shenzhen Browiner Tech Co., Ltd Or Huestis 150MC
Operation	Manual, square/rectangular field, field indicator lamp	Manual, square/rectangular field, field indicator lamp
Anatomical Programs	500+ Anatomical settings	500+ Anatomical settings
External Connectivity		
Connection	Wi-Fi and Ethernet Cable	Wi-Fi and Ethernet Cable
DICOM	YES	YES
Wi-Fi Communication with detectors	Wireless	Wireless
Standard		
Applied standard	IEC60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance IEC60601-1-2 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral	IEC60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance IEC60601-1-2 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral

Item	Proposed Device	Predicate Device
	standard: Electromagnetic compatibility - Requirements and tests. IEC60601-1-3 Medical electrical equipment Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-Ray equipment IEC60601-2-54 Medical electrical equipment Part 2-54: Particular requirements for the basic safety and essential performance of X-Ray equipment for radiography and radioscopy IEC62304 Medical device software – Software life-cycle processes 21CFR 1020.30 Diagnostic X-Ray systems and their major components 21CFR 1020.31 Radiographic equipment	standard: Electromagnetic compatibility - Requirements and tests. IEC60601-1-3 Medical electrical equipment Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-Ray equipment IEC60601-2-54 Medical electrical equipment Part 2-54: Particular requirements for the basic safety and essential performance of X-Ray equipment for radiography and radioscopy IEC62304 Medical device software – Software life-cycle processes 21CFR 1020.30 Diagnostic X-Ray systems and their major components 21CFR 1020.31 Radiographic equipment

9. Summary of non-clinical performance Tests

Digital Radiography System has been tested for electrical safety and electromagnetic compatibility (IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-54). The device also complies with FDA EPRC Performance Standard: 21CFR 1020.30 and 21CFR 1020.31. The software validation and verification testing was also performed and meets the requirements of IEC 62304. Usability was conducted according to IEC 62366-1. The results of nonclinical testing indicate that the Digital Radiography System is as safe and effective as the predicate device.

The Digital Radiography System has been tested to be in compliance with the following standards:

• 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

• 21CFR 1020.30 Diagnostic X-Ray systems and their major components

• 21CFR 1020.31 Radiographic equipment

10. 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.