December 20, 2023

Jiangsu Dynamic Medical Technology Co., Ltd.
% Doris Dong
General Manager
Shanghai CV Technology Co., Ltd.
Room 602, No. 19 Dongbao Road, Songjiang Area
SHANGHAI, SHANGHAI 201613
CHINA

Re: K231660
Trade/Device Name: Digital image scanner of dental
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: MUH
Dated: November 20, 2023
Received: November 24, 2023

Dear Doris Dong:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231660

Device Name
Digital image scanner of dental

Indications for Use *(Describe)*
Digital image scanner of dental is intended to be used for scanning and processing digital images exposed on IP Imaging Plate in dental applications.

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

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K231660
Date:	December 08, 2023
Type of 510(k) Submission:	Traditional 510(k)
Basis for 510(k) Submission:	New device
Owner:	JIANGSU DYNAMIC MEDICAL TECHNOLOGY CO., LTD. No.108 Xingpu Road, Lujia Town, Kunshan, Suzhou, Jiangsu, China 215331 Tel: 86-512-82627666 Email: technic2@dynamicgroup.cn
Contact:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add: Room 602, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description

Proprietary Name:	Digital image scanner of dental
Model:	DDT-100, DDT-100C, DDT-200, DDT-200C
Common Name:	Extraoral source x-ray system
Classification Name:	Extraoral source x-ray system
Regulation Number:	21 CFR 872.1800
Product Code:	MUH
Device Class:	2
Review Panel:	Radiology
Device Description:	Digital image scanner of dental is a dental device that scans IP imaging plates that have been exposed in place of dental X-ray film and allows the resulting images to be displayed on the screen and stored for later recovery. It will be used by licensed clinicians and authorized technicians for this purpose. The device is an intraoral Plate Scanner, which is designed to read out intraoral Plates of the size S0, S1, S2 and S3. The intraoral plates are put into the mouth of the patient, exposed to X-rays and then are read out with the device. The read-out-process is carried out with 630-645 nm laser. The laser beam is moved across the surface of the plate by an oscillating mirror. The laser beam stimulates the top coating of the plates, which consists of X-rays sensitive material. Depending on the exposed dose, the coating emits different levels of light. These light particles are then requisitioned by an optical sensor (Photo Multiplier tube/ PMT) and transferred into an electrical output signal. This signal is digitalized and is the data for the digital X-ray image. Before the plate is discharged, the remaining data is erased by a LED-PCB. The user chooses which size of plate he must use and prepares the device by inserting the appropriate plate

	insert into the device. He then exposes the plate and then puts the plate directly into the insert by pushing it out of the light protection envelope. The user closes the light protection over and starts the read-out process. After the read out process the picture is transmitted to the screen, the picture can be viewed, and the IP is erased and ready to use for the next acquisition.
Indications for use:	Digital image scanner of dental is intended to be used for scanning and processing digital images exposed on IP Imaging Plate in dental applications.

3. Predicate Device Information

Predicate 510(k) Number:	K212080
Marketing clearance date:	27/09/2021
Product name:	i-Scan Imaging Plate Scanner
Manufacturer:	Guilin Woodpecker Medical Instrument Co., Ltd

4. Comparison to predicate device

Parameters	**New Device**	**Predicate Device**	**Comparison**
510(k) number	K231660	K212080	--
Submitter	JIANGSU DYNAMIC MEDICAL TECHNOLOGY CO.,LTD.	Guilin Woodpecker Medical Instrument Co., Ltd.	--
Device name	Digital image scanner of dental	i-Scan Imaging Plate Scanner	--
Model	DDT-100,DDT-100C,DDT-200, DDT-200C	i-Scan	--
Regulation number	21 CFR 872.1800	21 CFR 872.1800	Same
Device class	II	II	Same
Product code	MUH	MUH	Same
Classification name	Extraoral source x-ray system	Extraoral source x-ray system	Same
Indications for use	Digital image scanner of dental is intended to be used for scanning and processing digital images exposed on IP Imaging Plate in dental applications.	i-Scan Imaging Plate Scanner is intended to be used for scanning and processing digital images exposed on IP Imaging Plate in dental applications.	Same
Prescription Use	Yes	Yes	Same
Site of Use	Hospitals and clinics	Hospitals and clinics	Same
Intended user	Operated and used by trained professionals with physician's guidance	Operated and used by trained professionals with physician's guidance	Same
Sterile	Non-Sterile	Non-Sterile	Same
Product Dimension (H*W*D)	DDT-100,DDT-100C:365*262*287mm DDT-200,DDT-200C:320*170*384mm	138*245.5*290.2mm	Similar Note 1
Product Weight	DDT-100,DDT-100C:9.3kg DDT-200,DDT-200C:9.3kg	4.5kg	

Mechanical design	The exposed and unwrapped plates are scanned using a laser with a certain wavelength of 630-645 nm. The scan pattern is line by line	The exposed and unwrapped plates are scanned using a laser with a certain wavelength of 651-665 nm. The scan pattern is line by line.	Similar Note 2
Electrical design	Light with a wavelength of approximately 380 nm is from the plate in proportion to the number of captured x-ray photons.This light is collected and formed into an image that may be viewed on a video display and stored for later recovery in a computer memory.	Light with a wavelength of approximately 380 nm is from the plate in proportion to the number of captured x-ray photons. This light is collected and formed into an image that may be viewed on a video display and stored for later recovery in a computer memory.	Same
Viewing the image	The touch screen only shows a preview which serves to provide an initial impression of the final x-ray image. For the purposes of diagnosis, the x-ray image must be viewed on a diagnostic monitor.The scanned images are displayed on an internal LCD or an external monitor using a computer and user software including image storage, retrieval and manipulation.	The touch screen only shows a preview which serves to provide an initial impression of the final x-ray image. For the purposes of diagnosis, the x-ray image must be viewed on a diagnostic monitor.The scanned images are displayed on an internal LCD or an external monitor using a computer and user software including image storage, retrieval and manipulation.	Same
Image scanning	Laser/Photomultiplier Tube	Laser/Photomultiplier Tube	Same
Erasing the residual image following scanning for plate reuse	The residual image is erased in the scanner by an inline erasing function.	The residual image is erased in the scanner by an inline erasing function.	Same
Transport/feed mechanism of imaging plate	The Plate realizes transmission movement through a conveyor belt, and the movement of the laser and the IP image board provides two orthogonal scanning directions.	The Plate realizes transmission movement through a conveyor belt, and the movement of the laser and the IP image board provides two orthogonal scanning directions.	Same
Imaging plate size	S0:22×35 mm S1:24×40 mm S2:31×41 mm S3:27×54 mm	Size 0: 22×35 mm Size 1: 24×40 mm Size 2: 31×41 mm Size 3: 27×54 mm	Same
Image data bit depth	16 bits	16 bits	Same
Contact body site	The device does not directly contact with human body or organ.	The device does not directly contact with human body or organ.	Same
Patient Contamination	Single patient use barrier	Single patient use barrier	Same

prevention	envelope encloses the imaging plate while in the patient's mouth.	envelope encloses the imaging plate while in the patient's mouth.	
Electronic User Manual	User manual is provided in printed form to the user.	User manual is provided in printed form to the user.	Same
Image Quality	Theoretical resolutions: 17 LP/mm	Theoretical resolutions: 10 or 33 LP/mm	Similar Note 3
RFID	No	No	Same
MTF	More than 45% at 3 lp/mm	More than 45% at 3 lp/mm	Same
DQE	More than 21.0% at 3 lp/mm	More than 21.0% at 3 lp/mm	Same
Software/Firmware/Microprocessor Control?	Digital Image Scanner Of Dental	Air-dental-woodpecker	Similar Note 4
External power source	100 to 240VAC, 50/60 Hz	100 to 240VAC, 50/60 Hz	Same
Compliance standards	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 61223-3-4 IEC 60825-1	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 62220-1 IEC 61223-3-4 IEC 60825-1 IEC 61010-1	Similar Note 5
Picture			Similar Note 1
Labeling	Meet FDA's requirement	Meet FDA's requirement	Same

Differences between New device and Predicate Device:

Note 1:

The weight, dimensions and appearance of the proposed device differ slightly from the predicate device,depending on the design and sales requirements of the product,but these differences are insignificant in terms of safety or effectiveness.

Note 2:

The operating principle of scanning the image plates with a laser of approximately the same wavelength,both the proposal device and the predicate device scans the plates with a line-by-line pattern.The scans collect the same data and process this for visual imaging. They support the same indications for use; the differences in the mechanical design does not raise issues of safety and effectiveness.

Note 3:

The subject device displays theoretical resolutions of 17-Line Pairs per mm, whereas the predicate shows theoretical resolutions of 10- or 33-Line Pairs per mm. And the image resolution of the proposed device is between the image resolution of the predicate device.The differences do not affect the operating principle and the Image Quality distinctness is such that it does not affect the effectiveness of the device.

Note 4:

The software is not the same between the subject device and the predicate, but both the subject and predicate have followed the FDA Guidance for the Content of Premarket for Submissions for Software Contained in Medical Devices.

Note 5:

According to the latest requirements, IEC 62220-1 is not applicable to digital X-ray imaging equipment for dental radiography. IEC 61010-1 is the test for laboratory equipment, we have done the test for ANSI AAMI ES60601-1, the standard is more stringent than IEC 61010-1.Other tests are the same as the predicate equipment, so it does not cause safety problems.

5. Summary of Non-clinical Testing

The safety and effectiveness of the Digital image scanner of dental were established and the substantial equivalence determination was supported by a series of performance testing, including Electrical safety and electromagnetic compatibility (EMC), Software Verification and Validation Testing, image reading and checking testing.

Electrical safety and electromagnetic compatibility (EMC)

General Requirements For Basic Safety And Essential Performance:This product has passed the IEC 60601-1 test and does not raise questions about safety effectiveness.

General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests:This product has passed the IEC 60601-1-2 test and does not raise questions about safety effectiveness.

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate devices. The test results demonstrated that the proposed device complies with the following standards:

1) ANSI AAMI ES60601-1: 2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD);

2) IEC 60601-1-2:2014, Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests;

Performance Testing

Acceptance tests - Imaging performance of dental X-ray:Imaging standard requirements were met for X-ray equipment.

Safety of laser products:Laser products have passed safety test.

1) IEC 61223-3-4 First edition 2000-03, Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray;

2) IEC 60825-1 Edition 2.0 2007-03, Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)].

Software Verification and Validation Testing

Software testing and V&V:As a result of unit level test, integration review and system level test, we hereby certify that all the functions those support system specification are proper. We confirm that software verification and validation test is properly accomplished.

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Image Reading and Checking Testing

Regarding image reading and checking testing, we performed image plates test and image accuracy and fidelity test respectively. Image plate test contains image plate imaging area, degree of attenuation, uniformity, image contrast, bit depth and spatial resolution or MTF test,etc..Image accuracy and fidelity test contains accuracy test, uniformity, image contrast,spatial resolution or MTF test,and image fidelity test.
The accuracy of image reading and checking results was verified by above testing.

6. Animal Study

Animal testing was not required for this submission.

7. Clinical Testing

Clinical testing was not required for this submission.

8. Substantial Equivalent (SE) Conclusion

Based upon comparison to the predicate devices, the proposed device is Substantial Equivalent (SE) to the predicate devices.