September 27, 2021

Guilin Woodpecker Medical Instrument Co., Ltd.
% Charles Mack
Principal Engineer
IRC
2950 E Lindrick Drive
CHANDLER AZ 85249

Re: K212080
Trade/Device Name: i-Scan Imaging Plate Scanner
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: MUH
Dated: June 21, 2021
Received: July 2, 2021

Dear Charles Mack:

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.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

, for

Thalia T. Mills, Ph.D
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K212080

Device Name

i-Scan Imaging Plate Scanner

Indications for Use *(Describe)*

i-Scan Imaging Plate Scanner 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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K212080 510(k) SUMMARY

Preparation Date:	September 26, 2021
Manufacturer's Name and Address:	Guilin Woodpecker Medical InstrumentCo., Ltd Information Industrial Park, Guilin National High-Tech Zone, Guilin City,Guangxi Province, China 541004
Corresponding Official:	Charles Mack
Telephone Number:	931-625-4938
Email Address:	charliemack@irc-us.com
Trade Name:	i-Scan Imaging Plate Scanner
Common Name(s):	system, x-ray, extraoral source,
Regulation Name(s):	Extraoral source x-ray system
Regulation Number(s):	21CFR872.1800
Product Code:	MUH
Device Class:	Class II
Predicate Device:	Duerr Dental AG
Predicate Trade Name:	ScanX Intraoral View
Predicate Common Name:	system, x-ray, extraoral source,
Predicate Regulation Name:	Extraoral source x-ray system
Predicate Regulation Number:	21CFR872.1800
Predicate 510(k):	K170733
Predicate Product Code:	MUH
Predicate Device Class:	Class II

Device Description:

i-Scan Imaging Plate Scanner 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 a personal computer 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 0, 1, 2 and 3. Intraoral plate scanners are state of the art since 2002 and are available in various designs from many companies around the world. 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 651-665 nm laser. The laser beam is moved across the surface of the plate by an oscillating MEMS mirror. The laser beam stimulates the top coating of the plates, which consists of X-ray 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. The data is transmitted via WIFI to a computer. 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 connected computer, the picture can be viewed, and the IP is erased and ready to use for the next acquisition.

Intended Use / Indications for Use

Scan Imaging Plate Scanner is intended to be used for scanning and processing digital images exposed on IP Imaging Plate in dental applications.

Comparison of Technological Characteristics with the Predicate Device

Characteristics	Submitted Device	Predicate Device	Discussion
Device Name and model	i-Scan Imaging Plate Scanner	ScanX Intraoral View	-
Device Photo			-
Manufacturer	Guilin Woodpecker Medical Instrument Co., Ltd	Duerr Dental AG	-
510(K) Number	Pending	K170733	-
Product Code	MUH	MUH	
Indication for Use	i-Scan Imaging Plate Scanner is intended to be used for scanning and processing digital images exposed on IP Imaging Plate in dental applications.	The ScanX Intraoral View is intended to be used for scanning and processing digital images exposedon Phosphor Storage Plates (PSPs) in dental applications.	Identical
Mechanical design	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.	The exposed and unwrapped plates are scanned in two orthogonal directions using a laser with a wavelength of approximately 650 nm.	*Note 1*
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.	Identical
Image scanning	Laser/Photomultiplier Tube	Laser/Photomultiplier Tube	Identical
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.	Identical

Characteristics	Submitted Device	Predicate Device	Discussion
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.	4.3" Touch Screen. 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.	Identical
Transport/feed mechanism	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 plates are transported by "beltways" down the axis of the cylinder past the slot. The motion of the laser and plates provides the two orthogonal scan directions. This is a continuous feed device that allows successive plates to be loaded as soon as the previous plates have moved past the slot.	*Note 2*
Phosphor Plates	Dental intraoral Size 0: 22 × 35 mm Size 1: 24 × 40 mm Size 2: 31 × 41 mm Size 3: 27 × 54 mm	Dental intraoral Size 0: 22 x 35 mm Size 1: 24 x 40 mm Size 2: 31 x 41 mm Size 3: 27 x 54 mm Size 4: 57 x 76 mm	*Note 3*
Image Quality	Theoretical resolutions: 10 or 33 LP/mm	Theoretical resolutions: 10, 20, 25 or 40 LP/mm	*Note 4*
MTF	More than 45% at 3 lp/mm	More than 45% at 3 lp/mm	Identical
DQE	More than 21.0% at 3 lp/mm	More than 7.5% at 3 lp/mm	*Note 5*
Image data bit depth	16 bits	16 bits	Identical
Body size and weight	138 x 245.5 x 290.2 [mm] (W x L x H) 4.5 [kg] (9.93 lbs.)	380 x 410 x 450 [mm] (W x L x H) 19.5 [kg] (42.99 lbs.)	*Note 6*
Imaging Software	Air-dental-woodpecker	DBSWIN/VistaEasy as cleared in K161444	*Note 7*
User interface	It will be used by dentists and authorized dental auxiliary personnel.	It will be used by dentists and authorized dental auxiliary personnel.	Identical
Energy Source AC	100 to 240VAC, 50/60 Hz	100 to 240VAC, 50/60 Hz	Identical
Patient Contamination prevention	Single patient use barrier envelope encloses the imaging plate while in the patient's mouth.	Single patient use barrier envelope encloses the imaging plate while in the patient's mouth.	Identical
RFID	No.	No.	Identical
Electronic User Manual	User manual is provided in printed form to the user.	User manual is provided in printed form to the user.	Identical
Applicable Standard	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 62220-1 IEC 61223-3-4 IEC 60825-1 IEC 61010-1	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 62220-1 IEC 61223-3-4 IEC 60825-1 IEC 61010-1	Identical

Discussion:

Note 1

The operating principle of scanning the image plates with a laser of approximately the same wavelength. The difference lies in scanning methodology. The subject device scans the plates with a line-by-line pattern and the predicate uses two orthogonal directional scans. The scans collect the same data and process this for visual imaging.

They support the same intended use; the differences in the mechanical design does not raise issues of safety and effectiveness.

Note 2

The subject device shows different constructive solutions for the performance itself, without influencing the intended use or safety. The operating principle is still the same. The image plates are scanned by means of that the image plate is transported in the scan position. After the scanning procedure the image plate is ejected from the device.

Note 3

The subject device offers four selections of phosphor plates whereas the predicate device is available in five sizes. This does not affect the effectiveness and the plate sizes that are offered by the subject device are the same size as the predicate device.

Note 4

The subject device displays theoretical resolutions of 10- or 33-Line Pairs per mm, whereas the predicate shows greater designation of Line Pairs per mm. 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 5

When the spatial frequency is lower than 3lp/mm, the MTF value is greater than 45%, and the DQE value is greater than 29%. The resolution and the quantum efficiency are both very high. Therefore, it can be considered that there is no aliasing, which is equivalent to the predicate device. When the spatial frequency is higher than 7lp/mm, the MTF value is only 5.1%, and the resolution is very low. It can be considered that there is a sign of aliasing. Coupled with the influence of quantum noise, the DQE value is less than 1%, so it does not have the ability of resolution. The difference in detective quantum efficiency was tested based on IEC62220-1 and there were minor deviations due

to the dental application of the radiography device. This difference did not adversely affect the image quality as demonstrated by the solid-state device testing.

Note 6

The size and weight of the subject and predicate device differ, but this has no bearing on the safety or effectiveness of the image plate scanning operations.

Note 7

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. Also, both the subject and predicate have passed performance testing, demonstrating the software functions to convert the digital data to acceptable images.

Performance Testing

Performance testing was provided in support of the substantial equivalence determination and to validate and verify that the Imaging Plate Scanner, Model i-Scan met all requirements of related international standards. The results of these tests demonstrate compliance with the requirements of the consensus standards noted below.

Non-clinical Testing

Performance Testing

- 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
- IEC 62220-1 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency
- 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)]
- IEC 60601-2-63 Edition1.1 2017-07, CONSOLIDATED VERSION Medical electrical equipment - Part 2-63: Requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
- IEC 60601-2-65 Edition 1.1 2017-05 CONSOLIDATED VERSION Medical electrical equipment - Part 2-65: Requirements for the basic safety and essential performance of dental intra-oral-X-ray equipment

FDA Guidance Documents

The following guidance documents were used in the development of the subject device:

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- FDA Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices
- FDA's cybersecurity guidance, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

EMC and Safety Testing

- ANSI AAMI ES60601-1 :2005/(R) 2012 and A1 :2012, C1 :2009/(R)2012 and A2:201 0/(R)2012 Medical electrical equipment - Part 1: General requirements for basic requirements: safety and essential performance (IEC 60601-1 :2005, MOD)
- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - requirements: Collateral standard: Electromagnetic compatibility – EMC Requirements and tests

Biocompatibility Information

No Biocompatibility testing was performed, as this device has no components which are patient contact devices.

Sterility Information

No sterility testing was accomplished, as this device is not delivered sterile, nor does it use require sterility.

Clinical Test:

No clinical study is included in this submission.

Conclusions:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Imaging Plate Scanner, Model i-Scan is substantially equivalent to the Duerr Dental AG, Inc. ScanX Intraoral View cleared under K170733 with respect to the indications for use, target populations, treatment method, and technological characteristics.

-END-