March 2, 2022

Hefei DentaFilm Medical Equipment Co., Ltd.
℅ Ming Chang Qiu
Management Representative
No. 98 Tangkou Road,
Economic and Technological Development Zone
Hefei, Anhui 230601
CHINA

Re: K214091
Trade/Device Name: Dental Image Plate Scanner, Model DFC-4T-SMART
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: January 5, 2022
Received: January 5, 2022

Dear Ming Qiu:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
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)*
K214091

Device Name
Dental Image Plate Scanner, Model DFC-4T-SMART

Indications for Use *(Describe)*

The Dental Image Plate Scanner, Model DFC-4T-SMART is intended to be used to scan dental X-ray latent images contained in the intraoral imaging plate and then generate, browse, process and review the intraoral dental digital X-ray image.

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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K214091

# Hefei DentaFilm Medical Equipment Co., Ltd

## Dental Image Plate Scanner, Model DFC-4T-SMART

Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-ray System
Regulatory Class: II
Product Code: MUH
Traditional 510(K) Submission Files

SECTION 5

510(k) Summary or 510(k) Statement

# 510(k) Summary

**Submission Number:** K214091

**Submitter**

Name: Hefei DentaFilm Medical Equipment Co., Ltd

Address: No. 98 Tangkou Road, Economic and Technological Development Zone, 230601 Hefei City, Anhui Province, People's Republic of China

Name of contact person: Ming Chang Qiu

Telephone: +86-551-63528008

Submission date: 2022-01-26

**Device**

Device trade name: Dental Image Plate Scanner, Model DFC-4T-SMART

Regulation Name: Extraoral Source X-ray System

Regulation class: 2

Regulation number: 21CFR 872.1800

Panel: Radiology

Product code: MUH

**Predicative device**

Predicate Submission Number: K192766

Predicate Device Trade Name: Digital Intraoral Imaging Plate System, Model F200, F210

Regulation Name: Extraoral Source X-ray System

Regulation number: 21CFR 872.1800

Panel: Radiology

Product code: MUH

**Device description**

The Dental Image Plate Scanner, Model DFC-4T-SMART is intended to scan and process image data contained in the intraoral imaging plate. Once the intraoral imaging

plate is inserted into the entrance of the scanner, the scanning program will be started to progressively scan the imaging plate, and move forward in the meantime to scan the imaging plate completely with the laser beam in a specified time. In the place where the laser is irradiated, blue fluorescence will be excited and the intensity of the fluorescence brightness is linearly related to the image data density at that point. The fluorescence will be collected by a high-efficiency photoconductor, which is positioned along the laser scanning line and then will be introduced into a photomultiplier tube, where it will be converted into a corresponding electrical signal. After the electrical signal is converted by A/D (analog/digital) converter in the electrical circuit, it can be used for digital image processing and then output to the image display, storage, or transmission communication system.

This Dental Image Plate Scanner, Model DFC-4T-SMART mainly consists of image plate scanner, power adapter, intraoral imaging plate and Dental image plate scanner control system software (Version: V1.0).

The image plate scanner is composed of lasers, optical scanners, photomultiplier tubes, amplifiers, A/D converters, image processing unit and output interfaces etc.

Dental image plate scanner control system software (DFC software) is mainly used to acquire and display the image data of the intraoral imaging plate as well as used for patient management, examination management, image storage, image printing etc.

Dental image plate scanner control system software (Version: V1.0) is of Moderate level of concern.

**Indication for use**

The Dental Image Plate Scanner, Model DFC-4T-SMART is intended to be used to scan dental X-ray latent images contained in the intraoral imaging plate and then generate, browse, process and review the intraoral dental digital X-ray image.

**Comparison of technological characteristics with the predicate device**

| Attribute | Subject device | Predicative device | Discussion/ Conclusion |
|---|---|---|---|
| Product name | Dental Image Plate Scanner, Model DFC-4T-SMART | Digital Intraoral Imaging Plate System, Model F200, F210 | / |
| Manufacturer | Hefei DentaFilm | Fussen Technology Co., | / |

| Attribute | Subject device | Predicative device | Discussion/ Conclusion |
|---|---|---|---|
| | Medical Equipment Co., Ltd | Ltd. | |
| 510(k) number | K214091 | K192766 | / |
| Device classification name | Class II | Class II | Same |
| Classification regulations | 21 CFR 872.1800 | 21 CFR 872.1800 | Same |
| Product code | MUH | MUH | Same |
| Product picture |   |   | / |
| Similarities | | | |
| Indication for Use | The Dental Image Plate Scanner is intended to be used to scan dental X-ray latent images contained in the intraoral imaging plate and then generate, browse, process and review the intraoral dental digital X-ray image. | Digital Intraoral Imaging Plate System is indicated for capturing, digitization and processing of intraoral x-ray images stored in imaging plate recording media. | Same meaning |
| Intended user | The Dental Image Plate Scanner is expected to be used only by professionally qualified dental/medical staffs. Typical user is a dental assistant with specific training for using dental diagnostic devices. | It is intended for uses in hospitals and clinics, and shall be operated and used by trained professionals with physician's guidance. | Same meaning |

| Attribute | Subject device | Predicative device | Discussion/ Conclusion |
|---|---|---|---|
| Working principle | The Dental Image Plate Scanner is intended to scan and process image data contained in the intraoral imaging plate. Once the intraoral imaging plate is inserted into the entrance of the scanner, the scanning program will be started to progressively scan the imaging plate, and move forward in the meantime to scan the imaging plate completely with the laser beam in a specified time. In the place where the laser is irradiated, blue fluorescence will be excited and the intensity of the fluorescence brightness is linearly related to the image data density at that point. The fluorescence will be collected by a high-efficiency photoconductor, which is positioned along the laser scanning line and then will be introduced into a photomultiplier tube, where it will be converted into a corresponding electrical signal. After | The imaging plate scanner functions as interpreting the latent image information stored in the imaging plate, and it consists of laser, optical scanner, photomultiplier, amplifier, A/D converter, image processing unit, output interface, etc. After a phosphor imaging plate is loaded into the imaging plate scanner inlet, start the scanning program to scan the imaging plate with latent image information to be interpreted row by row, move forwards at the same time, and it can be completely scanned by the laser beams once within set time. Blue florescence can be excited from parts radiated by the laser, and the intensity of the florescence brightness is in linear relationship with the density of the latent image information at the point. The florescence is collected by efficient photoconductor arranged along laser scanning line, is introduced into the photomultiplier, and is further converted into corresponding electric signals. After being transmitted into circuit system and subjected to | Same meaning |

| Attribute | Subject device | Predicative device | Discussion/ Conclusion |
|---|---|---|---|
| | the electrical signal is converted by A/D (analog/digital) converter in the electrical circuit, it can be used for digital image processing and then output to the image display, storage, or transmission communication system. | A/D (analog/digital) signal conversion, the electric signals can be used in digital image processing, and can be output to image display, storage or transmission communication system. | |
| Product structure | The image plate scanner is composed of lasers, optical scanners, photomultiplier tubes, amplifiers, A/D converters, image processing unit and output interfaces etc. | The imaging plate scanner consists of laser, optical scanner, photomultiplier, amplifier, A/D converter, image processing unit, output interface, etc. | Same |
| Software function design | Dental image plate scanner control system software (DFC software) is mainly used to acquire and display the image data of the intraoral imaging plate as well as used for patient management, examination management, image storage, image printing etc. | Digital intraoral imaging plate control system software (CRFC) is mainly used to read images from oral imaging plate and for patient and examination management and image storage and printing. | Same |
| Image scan design | the recorded image plate is scanned using a laser with a wavelength 635nm. | the recorded image plate is scanned using a laser. | Same |
| Erasing the residual image following | Automatically erasing plate | Automatically erasing plate | Same |

| Attribute | Subject device | Predicative device | Discussion/ Conclusion |
|---|---|---|---|
| scanning for plate reuse. | | | |
| Transport/feed mechanism of imaging plate | Imaging plate tray | Imaging plate holding groove | Same |
| Imaging plate | Intra Oral Dental Phosphor Plates<br>Size 0: 22 x 35 mm<br>Size 1: 24 x 40 mm<br>Size 2: 31 x 41 mm<br>Size 3: 27 x 54 mm | Intra Oral Dental Phosphor Plates<br>Size 0: 22 x 35 mm<br>Size 1: 24 x 40 mm<br>Size 2: 31 x 41 mm<br>Size 3: 27 x 54 mm | Same |
| Image data bit depth | 14 bits/pixel | 14 bits/pixel | Same |
| Data transmission interface | USB 2.0 port | USB 2.0 port | Same |
| Communication | DICOM3.0 | DICOM3.0 | Same |
| Patient Contamination prevention | In order to ensure hygiene, the imaging plate must be packed in an imaging plate protective bag during exposure procedure. | Use a barrier envelope to pack an imaging plate in order to ensure sanitation. | Same meaning |
| Differences | | | |
| Product size and weight | size (H×W×D): 296×170×196mm;<br>Wight: ≤7kg | size (H×W×D): 260×167×325mm<br>Weight: 5.2kg | differences on product size and weight will not affect the performance and safety of the scanner totally. |
| Imaging scanning | Laser/Photomultiplier Tube | Laser/Photomultiplier Tube | Same |
| Image Quality | ≥12lp/mm | 12lp/mm | Same |
| Pixel Size | 35μm | 35μm | Same |
| MTF | ≥41% at 3 lp/mm | not publicly available | The scanner is only used to transfer the recorded image in the |

| Attribute | Subject device | Predicative device | Discussion/ Conclusion |
|---|---|---|---|
| | | | image plate, and will not adversely affect the image quality as demonstrated by the solid-state device testing. |
| DQE | More than 9% at 3 lp/mm | not publicly available | The scanner is only used to transfer the recorded image in the image plate, and will not adversely affect the image quality as demonstrated by the solid-state device testing. |
| Imaging Software | DFC Software V1.0 | CRFC V2.0.2 | software is evaluated and validated according to the FDA Guidance. Such difference will not affect the performance and safety of the device. |
| External power source | Power adapter: input 100-240 V AC, 50/60Hz,1.4-0.7A Output: 15V ⎓ | Power adapter: Input 100-240V ～ 47-63Hz 1.62-0.72A Output DC15V 4.2A | slight difference on power adapter will |

| Attribute | Subject device | Predicative device | Discussion/ Conclusion |
|---|---|---|---|
| | 4.0A;60W MAX. | max. 63W | not affect the effectiveness and safety of the device. |

The subjective device and predicative device have the same intended use. The subject and predicative device have similar technological characteristics as evidenced by the table above. The differences in technological characteristics do not raise different questions of safety or effectiveness. Detailed information on difference discussion and conclusion refer to section 12 Substantial equivalence discussion.

**Summary of non-clinical testing (Performance testing-bench)**

The following performance data were provided to verify that the subject device met all design specifications and provided support of the substantial equivalence determination.

- Risk Analysis developed in accordance with ISO 14971:2019.
- IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- 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
- IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements
- IEC 62471: 2006 Photobiological safety of lamps and lamp systems
- Software development: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- Cybersecurity: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

**Summary of clinical testing**

No animal study and clinical studies are available for our device. Clinical testing was not required to demonstrate the substantial equivalence of the subject device to its predicate device.

**Conclusions**

The differences between the subjective device and its predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended. From the results of nonclinical testing described, it can be concluded that the subject device is substantially equivalent to the legally marketed predicate device.