July 22, 2022

PreXion Corporation
% Hiroaki Takahashi
General Manager
1-14-1, Kandasuda-cho
Chiyoda-ku, Tokyo 101-0041
JAPAN

Re: K221525
Trade/Device Name: PreXion3D Explorer PRO
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: May 24, 2022
Received: May 26, 2022

Dear Hiroaki Takahashi:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221525

Device Name
PreXion3D Explorer PRO

Indications for Use *(Describe)*
PreXion3D Explorer PRO is intended to produce two-dimensional digital x-ray images including panoramic and cephalometric image, and three-dimensional digital x-ray images of the dental, oral, maxillofacial region, ENT (Ear, Nose and Throat) and neck region at the direction of healthcare professionals as diagnostic support for adult and pediatric patients. Cephalometric imaging also includes the hand and wrist to obtain carpus images for growth and maturity assessment.

This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year old.

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.

510(k) Summary

PreXion3D Explorer PRO

K221525

1. Submission Sponsor

PreXion Corporation
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Chiyoda-ku, Tokyo 101-0041
Japan
Hiroaki Takahashi
General Manager, Quality Assurance & Regulatory Division
Email: px-ra@prexion.co.jp
Office number: +81-3-5297-7551

2. Submission Correspondent

Same as above

3. Date Prepared

May 24th, 2022

4. Device Identification

Trade/Proprietary Name:	PreXion3D Explorer PRO
Common/Usual Name:	OAS: Computed Tomography X-Ray System
Regulation Number:	OAS: 21 CFR 892.1750
Product Code:	OAS
Device Class:	Class II
Classification Panel:	Radiology

5. Legally Marketed Predicate Device(s)

Predicate Device: K203784, PreXion3D Explorer PRO (Model: P03A), PreXion Corporation

6. Indication for Use Statement

PreXion3D Explorer PRO is intended to produce two-dimensional digital x-ray images including panoramic and cephalometric image, and three-dimensional digital x-ray images of the dental, oral, maxillofacial region, ENT (Ear, Nose and Throat) and neck region at the direction of healthcare professionals as diagnostic support for adult and pediatric patients. Cephalometric imaging also includes the hand and wrist to obtain carpus images for growth and maturity assessment.

This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year old.

7. Device Description

PreXion3D Explorer PRO consists of a scanner, which is used for generating X-ray and detecting image data, and a console, which is used for operating the scanner and managing the data. The scan data acquired by the scanner will be transferred to the Console. PreXion3D Explore Image Analysis System will then perform the image analysis (2D/3D) or image edition (creating cross-section diagram, etc.), and output the image to a printer.

X-ray image data is acquired while the rotation arm is rotating around the secured "patient's head" at a constant speed. X-rays, which are emitted from X-ray generator (built in one side of rotation arm), pass through a patient and are detected by the flat panel detector (built in the other side of rotation arm). The detected X-ray absorption data is used to process image reconstruction on the Console to create the 3D image (CT scan), the tomographic image (CT scan, Panoramic scan) and Cephalometric Scan.

The operating principle of the device is as follows.

<X-ray generation principle>

X-rays are generated by the conversion of electron kinetic energy.

Part of the kinetic energy which is generated when electrons moving at high speed are decelerated inside matter becomes the conversion source.

Use a high-voltage transformer to boost the commercial voltage (100 to 240 V) to direct current high voltage (several tens of kV) and apply it to the X-ray tube to accelerate the X-ray tube's thermal electrons, and then the X-ray will be generated.

The change in the voltage (tube voltage) and current (tube current) applied to the X-ray tube brings the following features.

• The higher the X-ray tube voltage is, the greater the penetration strength of X-rays is.

• The higher the current (tube current) is, the more the X-ray dose is.

With the consideration of the above features, X-ray devices are designed to be able to control the X-ray dose and strength according to the intended use.

<CT Scan principle and Panoramic Scan principle>

X-ray photography is acquired while the rotation arm is rotating around the secured "patient's head" at a constant speed.

X-rays, which are emitted from X-ray generator (built in one side of rotation arm), pass through a patient and are detected by the flat panel detector (built in the other side of rotation arm).

The detected X-ray absorption data is used to process image reconstruction on the Console to create the 3D image (CT scan) and the tomographic image (CT scan, Panoramic scan).

- Cephalometric Exposure

Based on cephalometric radiography, a plain radiographic image of the properly positioned "patient's head" between X-ray generator and flat panel detector with stable magnification ratio, can be acquired. Also, the image of "patient's hand" can be obtained.

<Software>

PreXion3D Explorer PRO consists of a scanner, which is used for generating X-ray and detecting image data, and a Console, which is used for operating the scanner and managing the data. The scan data acquired by the scanner will be transferred to the Console. PreXion3D Explorer PRO Image Analysis System will then perform the image analysis (2D/3D) or image edition (creating cross-section diagram, etc.), and output the image to a printer.

X-ray image data is acquired while the rotation arm is rotating around the secured "patient's head" at a constant speed.

X-rays, which are emitted from X-ray generator (built in one side of rotation arm), pass through a patient and are detected by the flat panel detector (built in the other side of rotation arm).

The detected X-ray absorption data is used to process image reconstruction on the Console to create the 3D image (CT scan), the tomographic image (CT scan, Panoramic scan) and Cephalometric Scan.

For CT and Panoramic scan, the detected data is reconstructed using filtered-back-projection method. In the case of Cephalometric scan, the acquired 2D data is output as it is.

The software is unchanged from the predicates in terms of function.

- Software Level of Concern

  The software level of concern for the PreXion3D Explorer PRO is Moderate. The rationale is as follows:

  Even prior to mitigation of hazards, there is no risk of serious injury or death associated with this software. Excessive X-ray irradiation can be considered as a risk of serious injury, but it is limited in scope by a hardware timer. A hardware activated buzzer indicating exposure and an emergency switch are also provided. As such, there is a risk of injury associated with the software, but not serious injury.

8. Substantial Equivalence Discussion

The following table compares the PreXion3D Explorer PRO to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

	Subject Device	**Predicate Device**	**Comparison to Predicate**
Manufacturer	**PreXion Corporation**	**PreXion Corporation**	
Trade Name	**PreXion3D Explorer PRO**	**PreXion3D Explorer PRO**	
Model Name	**P03B**	**P03A**	N/A
510(k) Number	K221525	K203784	N/A
Product Code	OAS	OAS	Same
Regulation Number	OAS: 21 CFR 892.1750	OAS: 21 CFR 892.1750	Same
Regulation Name	OAS: Computed tomography x-ray system	OAS: Computed tomography x-ray system	Same
Device Classification Name	X-Ray, Tomography, Computed, Dental	X-Ray, Tomography, Computed, Dental	Same

Indications for use:	PreXion3D Explorer PRO is intended to produce two dimensional digital panoramic and cephalometric images, and three-dimensional digital x-ray images of the maxillofacial, and ENT (Ear, Nose and Throat) and neck region at the direction of healthcare professionals as diagnostic support for adult and pediatric patients. Cephalometric imaging also includes the hand and wrist to obtain carpus images for growth and maturity assessment. This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year old.	PreXion3D Explorer PRO is intended to produce two dimensional digital panoramic and cephalometric images, and three-dimensional digital x-ray images of the maxillofacial, and ENT (Ear, Nose and Throat) and neck region at the direction of healthcare professionals as diagnostic support for adult and pediatric patients. Cephalometric imaging also includes the hand and wrist to obtain carpus images for growth and maturity assessment. This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year old.	Same
Patient/User Characteristics			
Target Population	Children aged 6 (except infants) to elderly	Children aged 6 (except infants) to elderly	Same
Anatomical Site	The dental, oral, maxillofacial region ENT (Ear, Nose and Throat) and neck region	The dental, oral, maxillofacial region ENT (Ear, Nose and Throat) and neck region	Same
Users	Health care professionals	Health care professionals	Same
Technological Characteristics and Performance			
Patient Contact Material	CHIN REST: polycarbonate Forehead Holder: silicone rubber HANDLE GRIP: silicone rubber	CHIN REST: polycarbonate Forehead Holder: silicone rubber HANDLE GRIP: silicone rubber	Same
Sterility	Non-sterile	Non-sterile	Same

X-ray Generation Device	**Tube Voltage**	90-110KV	90-110KV	Same
	Pulse Exposure function	Yes	Yes	Same
	Tube Current	1-5.3mA	1-5.3mA	Same
	Focal Spot Size	0.3mm x 0.3mm	0.3mm x 0.3mm	Same
Collimator Size		CT scan (Face) /CT-Panorama Scan (Face): 33.6mm x 27mm CT scan (Arch): 20.6mm x 20.8mm CT scan (Full): 23mm x 27mm CT scan (Teeth) : 10.5mm x 10.2mm Panoramic Scan: 1mm x 24.2mm Cephalometric Exposure: 22.0mm x 17.6mm	CT scan (Face) /CT-Panorama Scan (Face): Same CT scan (Arch): Same CT scan (Full): Same CT scan (Teeth): Same Panoramic Scan: Same Cephalometric Exposure: 23.6mm x 18.7mm	Similar (Same except for Cephalometric Exposure)
X-ray Image Capturing Device	**Detector**	FPD (TFT)	FPD (TFT)	Same
	Pixel Size	248 μm x248μm (With binning) (CT, CT-Panoramic, Panoramic) 124 μm x124μm (Without binning) (CT, CT-Panoramic, Panoramic, Ceph)	248 μm x248μm (With binning) (CT, CT-Panoramic, Panoramic) 124 μm x124μm (Without binning) (CT, CT-Panoramic, Panoramic, Ceph)	Same
	Pixel Number	1024x1280(With binning) (CT, CT-Panoramic) 2560x2048 (Without binning) (CT, CT-Panoramic, Ceph) 1900 x 120 (Panoramic) 2560 x 2048 (Cephalometric)	1024x1280(With binning) (CT, CT-Panoramic) 2560x2048 (Without binning) (CT, CT-Panoramic, Ceph) 1900 x 120 (Panoramic) 2560 x 2048 (Cephalometric)	Same Same Same Same
	Size of Area Receiving X-ray	253.95mm x 317.44mm (CT, CT-Panoramic) 230mm x 15mm (Panoramic)	253.95mm x 317.44mm (CT, CT-Panoramic) 230mm x 15mm (Panoramic)	Same Same

		239mm x 302mm (Ceph)	253.95mm x 317.44mm (Ceph)	Smaller
	Number of Bits	16bits (CT, Panorama, Ceph)	16bits (CT, Panorama, Ceph)	Same
Scanner	**SID/SOD**	700mm/ 420mm (CT, CT-Panoramic, Panoramic) 1000mm / 840mm (Ceph)	700mm/ 420mm (CT, CT-Panoramic, Panoramic) 1000mm / 840mm (Ceph)	Same
	Dimension (WxDxH)	1,112 mm x 1,558 mm x 2330 mm (CT, CT-Panoramic, Panoramic) 1164 mm x 1690 mm x 2330 mm (with Ceph)	1,112 mm x 1,558 mm x 2330 mm (CT, CT-Panoramic, Panoramic) 1164 mm x 1690 mm x 2330 mm (with Ceph)	Same
	Weight	230 kg (CT, CT-Panoramic, Panoramic, Ceph)	230 kg (CT, CT-Panoramic, Panoramic, Ceph)	Same
Imaging Mode		CT scan, CT-Panoramic, Panoramic scan, Cephalometric radiography	CT scan, CT-Panoramic, Panoramic scan, Cephalometric radiography	Same
Panoramic Scan Performance (Scan Time)		8-16sec	8-16sec	Same
Cephalometric Radiography (Scan Time)		0.16sec	0.16sec	Same
CT Scan Performance	**Scan Time**	10-20sec	10-20sec	Same
	FOV (Voxel Size)	Diameter 150mm x H156mm (0.100 - 0.200mm) Diameter 150mm x H100mm (0.100 - 0.200mm) Diameter 100mm x H100mm (0.100 - 0.200mm) Diameter 50mm x H50mm (0.100 - 0.200mm)	Diameter 150mm x H156mm (0.100 - 0.200mm) Diameter 150mm x H100mm (0.100 - 0.200mm) Diameter 100mm x H100mm (0.100 - 0.200mm) Diameter 50mm x H50mm (0.100 - 0.200mm)	Same
Applied Standard				
Electrical Safety Standard		ANSI/AAMI ES60601-1	ANSI/AAMI ES60601-1	Same

Electromagnetic Compatibility Standard	IEC 60601-1-2	IEC 60601-1-2	
Radiation Safety Standard	IEC 60601-1-3	IEC 60601-1-3	
Electrical Equipment Usability Safety Standard	IEC 60601-1-6	IEC 60601-1-6	
Usability Engineering Standard	IEC 62366	IEC 62366	
Software Lifecycle Process Standard	IEC 62304	IEC 62304	
Essential performance of dental extra-oral X-ray equipment Standard	IEC 60601-2-63	IEC 60601-2-63	
Acceptance tests of Imaging performance of dental X-ray equipment Standard	IEC 61223-3-4	IEC 61223-3-4	
Acceptance tests of Imaging performance of computed tomography X-ray equipment Standard	IEC 61223-3-5	IEC 61223-3-5	
Laser Safety Standard	IEC 60825-1	IEC 60825-1	
Risk Management Standard	ISO 14971	ISO 14971	
DICOM Standard	NEMA PS 3.1 - 3.20	NEMA PS 3.1 - 3.20	
Biocompatibility Standard Compliance	ISO 10993-1	ISO 10993-1	
Biocompatibility Standard Compliance	ISO 10993-5	ISO 10993-5	
Biocompatibility Standard Compliance	ISO 10993-10	ISO 10993-10	

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of PreXion3D Explorer PRO and in showing substantial equivalence to the predicate device, PreXion Corporation completed a number of non-clinical performance tests. The PreXion3D Explorer PRO meets all the requirements for overall design, biocompatibility, performance, and electrical safety results confirming that the design output meets the design inputs and specifications for the device.

The PreXion3D Explorer PRO passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing per ISO 10993-1, ISO 10993-5 and ISO 10993-10
- Electrical safety testing per ANSI/AAMI ES 60601-1, IEC 60601-1-3 and IEC 60601-1-6
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2
- Dental extra-oral X-ray equipment testing per IEC 60601-2-63
- Software verification and validation IEC 62304
- Acceptance testing of X-ray equipment per IEC 61223-3-4 and IEC 61223-3-5
- Storage and Transport Testing per ISO 4180
- IEC 62366-1:2015 Usability engineering to medical devices
- Software Documentation per: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Establish the substantial equivalence of an SSXI to a previously cleared conventional radiographic SSXI per: "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices"
- Cybersecurity Activities per: "Cybersecurity-for-Networked-Medical-Devices-Containing-Off-the-Shelf-(OTS)-Software---Guidance-for-Industry", "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

The PreXon3D Explorer PRO, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.