



January 12, 2023

PreXion Corporation
% Kenji Tanaka
Quality Assurance and Regulatory Affairs Division
1-14-1, Kandasuda-cho
Chiyoda-ku, Tokyo 101-0041
JAPAN

Re: K222150
Trade/Device Name: PreXion3D Expedition
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: December 1, 2022
Received: December 15, 2022

Dear Kenji Tanaka:

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,

 2023.01.12
09:13:16
-05'00'

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

Indications for Use

510(k) Number (if known)
K222150

Device Name
PreXion3D Expedition

Indications for Use (Describe)

PreXion3D Expedition 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

PreXion3D Expedition

K222150

1. Submission Sponsor

PreXion Corporation
1-14-1, Kandasuda-cho,
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

July 13th, 2022

4. Device Identification

Trade/Proprietary Name: PreXion3D Expedition
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) and Reference Device

Predicate Device: K203784, PreXion3D Explorer PRO, PreXion Corporation
Reference Device: K181983, PreXion3D Excelsior, PreXion Corporation

6. Indication for Use Statement

PreXion3D Expedition 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 Expedition 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 Expedition 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 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 Expedition 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 Expedition 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	<u>Reference Device</u>	Comparison to Predicate
Manufacturer	PreXion Corporation	PreXion Corporation	PreXion Corporation	
Trade Name	PreXion3D Expedition	PreXion3D Explorer PRO	PreXion3D Excelsior	
510(k) Number	K222150	K203784	K181983	N/A
Product Code	OAS	Same	Same	Same
Regulation Number	OAS: 21 CFR 892.1750	Same	Same	Same
Regulation Name	OAS: Computed tomography x-ray system	Same	Same	Same
Device Classification Name	X-Ray, Tomography, Computed, Dental	Same	Same	Same

<p>Indications for use:</p>	<p>PreXion3D Expedition 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.</p>	<p>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.</p>	<p>PreXion3D Excelsior is intended to produce two-dimensional digital x-ray images including panoramic and cephalometric images, and three-dimensional digital x-ray images of the dental (oral), maxillofacial, and ENT (Ear, Nose and Throat) 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.</p>	<p>Same</p>
Patient/User Characteristics				
<p>Target Population</p>	<p>Children aged 6 (except infants) to elderly</p>	<p>Same</p>	<p>Same</p>	<p>Same</p>
<p>Anatomical Site</p>	<p>The dental, oral, maxillofacial region ENT (Ear, Nose and Throat) and neck region</p>	<p>Same</p>	<p>Same</p>	<p>Same</p>
<p>Users</p>	<p>Health care professionals</p>	<p>Same</p>	<p>Same</p>	<p>Same</p>
Technological Characteristics and Performance				

Patient Contact Material		CHIN REST: polycarbonate Forehead Holder: silicone rubber HANDLE GRIP: silicone rubber	Same	CHINREST: polycarbonate Forehead Holder: silicone rubber	Same
Sterility		Non-sterile	Same	Same	Same
X-ray Generation Device	Tube Voltage	90-110KV	<u>Same</u>	60-110KV	<u>Same</u>
	Pulse Exposure function	Yes	<u>Same</u>	Same	Same
	Tube Current	1-5.3mA	<u>Same</u>	1-6mA	<u>Same</u>
	Focal Spot Size	0.3mm x 0.3mm	Same	Same	Same
X-ray Image Capturing Device (CT, Panoram a)	Detector	FPD (TFT)	Same	Same	Same
	Photo Diode	IGZO TFT matrix _____	TFT:a- Si(Amorphous Silicon)	TFT:a-Si _____	<u>Different</u>
	scintillator	CsI:TI	<u>Same</u>	<u>Same</u>	<u>Same</u>
	Manufacturer	PreXion Corporation	Vieworks Co. Ltd.,	<u>Same</u>	<u>Different</u>
	Pixel Size	248 μm x248μm (With binning) (CT, CT-Panoramic, Panoramic)	Same	125 μm x125μm,125μm x250μm (CT)	Same
		124 μm x124μm (Without binning) (CT, CT-Panoramic, Panoramic)	Same	125 μm x 125μm (Panoramic)	Same
	Pixel Number	640 x 768 (With binning) (CT, CT-Panoramic)	1024x1280(With binning) (CT, CT-Panoramic)	1024x1280(CT, CT- Panoramic)	Regarding CT, CT- Panoramic, smaller
1280 x 1536 (Without binning) (CT, CT-Panoramic)		2048 x 2560 (Without binning) (CT, CT-Panoramic, Ceph)			
120 x 1280 (Panoramic)		120 x 2560 (Panoramic)	<u>192 x 1280</u> (Panoramic)	Similar	
Size of Area	158mm x 190mm (CT, CT-Panoramic)	253.95mm x 317.44mm (CT, CT-Panoramic)	128mm x 160mm (CT)	Smaller than predicate device	

	Receiving X-ray	158mm x 15mm (Panoramic)	317.44mm x 15mm (Panoramic)	160mm x 24mm (Panoramic)	
	Number of Bits	16bits (CT, Panorama)	Same	16bits (CT, Panorama)	Same
X-ray Image Capturing Device (Cephalometric)	Detector	FPD (TFT)	Same	Same	Same
	Photo Diode	IGZO TFT matrix	TFT:a-Si(Amorphous Silicon)	TFT:a-Si	Different
	scintillator	GOS	CsI:TI	Same	Different
	Manufacturer	PreXion Corporation	Vieworks Co. Ltd.,	Same	Different
	Pixel Size	124 μm x 124μm (Ceph)	Same	140 μm x 140μm (Ceph)	Same
	Pixel Number	2560 x 2048 (Cephalometric)	Same	2112x1754 (Cephalometric)	Same
	Size of Area Receiving X-ray	253.95mm x 317.44mm (Ceph)	Same	295.68 x 245.56mm (Ceph)	Same
	Number of Bits	16bits (Ceph)	Same	14bits (Ceph)	Same
Scanner	SID/SOD	700mm/ 470mm (CT, Panoramic) 1735mm / 15000mm (Ceph)	700mm/ 420mm (CT, Panoramic) 1000mm / 840mm (Ceph)	Same (CT, Panoramic) Same (Ceph)	Similar
	Dimension (WxDxH)	1160 mm x 1207 mm x 2330 mm (CT, CT-Panoramic, Panoramic) 1833 mm x 1207 mm x 2330 mm (Ceph)	1112 mm x 1267 mm x 2330 mm (CT, CT-Panoramic, Panoramic, Ceph)	930 mm x 1230 mm x 2220 mm (CT, Panoramic) 1747 mm x 1230 mm x 2220 mm (with Ceph)	Similar
	Weight	170 kg (CT, Panoramic) 198kg (Ceph)	230 kg (CT, Panoramic, Ceph)	165 kg (CT, Panoramic) 200kg (Ceph)	Similar
Imaging Mode		CT scan, Panoramic scan, Cephalometric radiography	Same	Same	Same
Panoramic Scan Performance (Scan Time)		8-16sec	8-16sec	8-16sec	Same

Cephalometric Radiography (Scan Time)		0.16 sec	0.16sec	0.5-0.8sec	Same
CT Scan Performance	Scan Time	8-25sec	10-20sec	5.2-25.6sec	Similar
	FOV (Voxel Size)	Diameter 140mm x H150mm (0.100 - 0.200mm)	Diameter 150mm x H156mm (0.100 - 0.200mm)	Diameter 150mm x H130mm(0.100 - 0.200mm)	Similar
		Diameter 125mm x H100mm (0.100 - 0.200mm)	Diameter 150mm x H100mm (0.100 - 0.200mm)	Diameter 100mm x H81mm (0.100 - 0.200mm)	
		Diameter 80mm x H80mm (0.100 - 0.200mm)	Diameter 100mm x H100mm (0.100 - 0.200mm)	Diameter 100mm x H50mm (0.100 - 0.200mm)	
		Diameter 50mm x H50mm (0.100 - 0.200mm)	Diameter 50mm x H50mm (0.100 - 0.200mm)	Diameter 50mm x H50mm (0.100 - 0.200mm)	
Applied Standard					
Electrical Safety Standard	ANSI/AAMI ES60601-1	Same	Same	Same	
Electromagnetic Compatibility Standard	IEC 60601-1-2				
Radiation Safety Standard	IEC 60601-1-3				
Electrical Equipment Usability Safety Standard	IEC 60601-1-6				
Usability Engineering Standard	IEC 62366				
Software Lifecycle Process Standard	IEC 62304				
Essential performance of dental extra-oral X-ray equipment Standard	IEC 60601-2-63				
Acceptance tests of Imaging performance of dental X-ray equipment Standard	IEC 61223-3-4				
Acceptance tests of Imaging performance of computed	IEC 61223-3-5				

tomography X-ray equipment Standard				
Laser Safety Standard	IEC 60825-1			
Risk Management Standard	ISO 14971			
DICOM Standard	NEMA PS 3.1 - 3.20			
Biocompatibility Standard	ISO 10993-1			
Compliance Biocompatibility Standard	ISO 10993-5			
Compliance Biocompatibility Standard	ISO 10993-10			

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of PreXion3D Expedition and in showing substantial equivalence to the predicate device, PreXion Corporation completed a number of non-clinical performance tests. The PreXion3D Expedition 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 Expedition 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

No clinical testing was performed and that the non-clinical testing provided 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 Expedition, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.