DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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PreXion Corporation
% Mr. Shumpeita Torii
Director
Funai Tokyo Technology Center Building, 1-14-1 Kandasuda-cho
Chiyoda-ku, Tokyo 101-0041
JAPAN

October 3, 2016

Re: K161881
Trade/Device Name: PreXion3D Excelsior
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: September 8, 2016
Received: September 9, 2016

Dear Mr. Torii:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161881

Device Name
PreXion3D Excelsior

Indications for Use *(Describe)*
PreXion3D Excelsior 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) 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.

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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

510(k) Number: K161881

5.1 Applicant Information

Date Prepared:	Sep. 8th, 2016
Company Name and Address:	PreXion Corporation Funai Tokyo technology center building, 1-14-1 Kandasuda-cho, Chiyoda-ku Tokyo, 101-0041 Japan
Contact Person:	Mr. Shumpeita Torii Director, Quality Assurance and Regulatory Division Phone: +81-3-5297-7551 FAX: +81-3-5297-7552 Email: torii@prexion.co.jp

5.2 Device Information

Device Type:	Dental Cone-beam Computed Tomography
Regulation Description:	Computed Tomography X-Ray System
Review Panel:	Radiology
Regulation Number:	21 CFR 892.1750
Product Code:	OAS
Device Class:	II
Device Name:	Prexion3D Excelsior

5.3 Predicate Devices

The legally marketed devices to which substantial equivalence is being claimed are:

510(k) Number:	K122199	K103659	K133620
Applicant:	THE YOSHIDA DENTAL MFG. CO., LTD.	Trophy	Imaging Sciences International, LLC
Device Name:	PREXION 3D ECLIPSE	CS 9300 and CS 9300C	i-CAT FLX Cone Beam 3D and 2D Panoramic Dental Imaging System
Regulation Number:	21 CFR 892.1750	21 CFR 892.1750	21 CFR 892.1750
Product Code:	OAS	OAS	OAS
Device Class:	II	II	II

5.4 Device Description

PreXion3D Excelsior 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 Excelsior 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.

During scanning, X-rays are generated from the x-ray tube head mounted in the arm of the scanner and the x-rays passing through a patient are then detected by the flat panel detector of the scanner under the control of the firmware inside and the console software installed on the qualified Computer. The detected x-ray absorption data is processed by the console software to reconstruct the diagnostic images. The PreXion3D Excelsior has three operation modes, CT scan, Panoramic scan and Cephalometric exposure.

5.5 Intended Use/Indications for Use

PreXion3D Excelsior 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) 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.

5.6 Technological Characteristics

The subject device compares to the legally marketed devices as follows:

Device	**Subject Device**	**Predicate device**		
	PreXion3D Excelsior	**PREXION 3D ECLIPSE (K122199)**	**CS 9300 and CS 9300C (K103659)**	**i-CAT FLX Cone Beam 3D and 2D Panoramic Dental Imaging System (K133620)**
Intended Use/Indications for Use	PreXion3D Excelsior 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) region at the	PREXION3D ECLIPSE is intended to produce two-dimensional digital panoramic and cephalometric images, and three-dimensional digital x-ray images of the dento-maxillo-facial region at the direction of healthcare	The CS 9300 and CS 9300C are systems intended to produce two-dimensional and three-dimensional digital x-ray images of the dento-maxillo-facial, and ENT (Ear, Nose and Throat) regions at the direction of healthcare	Devices of the i-CAT family consist of an x-ray system that uses a cone beam with a rotational sequence, providing two dimensional images and three dimensional volume reconstructions of the head area,

Device		Subject Device	Predicate device		
		PreXion3D Excelsior	**PREXION 3D ECLIPSE (K122199)**	**CS 9300 and CS 9300C (K103659)**	**i-CAT FLX Cone Beam 3D and 2D Panoramic Dental Imaging System (K133620)**
		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.	professionals as diagnostic support.	professionals as diagnostic support for pediatric and adult patients. In addition, the CS 9300C is intended to produce cephalometric images. This includes imaging the hand and wrist to obtain the carpus image for growth and maturity assessment.	which includes ENT and maxillofacial areas (such as TM Joint studies, mandible & maxilla for implant planning, sinuses), for use in planning and diagnostic support in adult and pediatric care. Devices of the i-CAT family comprise a package of software modules capable of handling 2D and 3D data. This includes 3D reconstruction, storage, retrieval, viewing, and processing of 2D and 3D-image data.
X-ray Generation Device	Tube Voltage	60-110KV	50-90 kV	60 - 90 kV	84-120 kV 94 kV (Panoramic) 84 kV (Panoramic small)
	Pulse Exposure function	Yes	N/A	Yes	Yes
	Tube Current	1-6mA	2.6-4 mA	2 - 15 mA	3-7mA 5mA (Panoramic and Panoramic small)
	Focal Spot Size	0.3mm	0.2 mm	0.7 mm	0.5mm
X-ray Image Capt	Detector	FPD (TFT)	FPD (CMOS)	FPD (TFT)	FPD (TFT)
	Pixel Size	125 µm x125µm,125µm	200 µm (CT)	127 µm	127um x 127um 254um x 254um

Device		Subject Device	Predicate device		
		PreXion3D Excelsior	**PREXION 3D ECLIPSE (K122199)**	**CS 9300 and CS 9300C (K103659)**	**i-CAT FLX Cone Beam 3D and 2D Panoramic Dental Imaging System (K133620)**
uring Device		x250µm(CT) 125 µm x 125µm(Panoramic) 140 µm x 140µm (Ceph)	100 µm (Panoramic) 54 µm (Ceph)		
	Pixel Number	1280x1024 (CT) 100x1280 (Panoramic) 2112x1754 (Cephalometric)	640x656 (CT) 80x1312 (Panoramic) 128x4080 (Ceph)	64 x 1536 (Panoramic)	1536 x 1920 768 x 960
	Size of Area Receiving X-ray	160mm x 128mm (CT) 160mm x 12.5mm (Panoramic) 295.68 x 245.56mm (Ceph)	128.1 mm x 131.3 mm (CT) 8 mm x 131.3 mm (Panoramic) 6.9 mm x 312 mm (Ceph)	5 x 149 mm max (Panoramic)	242mm x 192mm (CT) 10mm x 100mm (Panoramic)
	Number of Bits	16bits (CT, Panorama) 14bits (Ceph)	14 bits (CT, Panoramic) 16 bits (Ceph)	14 Bits	16 bits
Scanner	SID/SOD	700mm/ 470mm (CT, Panoramic) 1650mm / 1500mm (Ceph)	620 mm / 400 mm (CT, Panoramic) 1650 mm / 1500 mm (Ceph)	615 mm (SID)	714mm / 495mm
	Dimension (WxDxH)	930 mm x 1230 mm x 2220 mm (CT, Panoramic) 1747 mm x 1230 mm x 2220 mm (with Ceph)	1245 mm x 1288 mm x 2045 mm (CT, Panoramic) 1805 mm x 1288 mm x 2045 mm (Ceph)	1158 mm x 1595 mm x 2378 mm	1222mm x 1340mm x 1820mm

Device		Subject Device	Predicate device		
		PreXion3D Excelsior	**PREXION 3D ECLIPSE (K122199)**	**CS 9300 and CS 9300C (K103659)**	**i-CAT FLX Cone Beam 3D and 2D Panoramic Dental Imaging System (K133620)**
	Weight	165 kg (CT, Panoramic) 200kg (Ceph)	260 kg (CT, Panoramic) 300 kg (Ceph)	160 kg (CT, Panoramic) 190 kg (Ceph)	231kg
Imaging Mode		CT scan, Panoramic scan, Cephalometric radiography	CT scan, Panoramic scan, Cephalometric radiography	CT scan, Panoramic scan, Cephalometric radiography	CT scan, Panoramic scan
Panoramic Scan Performance (Scan Time)		4-16sec	Standard mode: 16 sec	4 – 16 sec	18.3 -20.0 sec
Cephalometric Radiography (Scan Time)		0.5-0.8 sec	LA, PA, Carpus: 8, 10, 12, 15 sec	0.1 – 3.2 sec	N/A
CT Scan Performance	Scan Time	6.9-25.6sec	Light mode: 8.7 sec High Definition mode: 8.7 sec Ultra High Definition mode: 17.4 sec Wide mode: 9.1 sec x 2	12 – 20 sec 28 sec	4.8 – 26.9 sec
	FOV (Voxel Size)	Diameter 100mm x H76mm (0.100 - 0.200mm) Diameter 150mm x H75 (0.200mm) Diameter 100mm x H50mm (0.100 - 0.200mm) Diameter 50mm x H50mm (0.100 - 0.200mm)	Light mode, High Definition mode, Ultra High Definition mode: Diameter 81 mm, H 75 mm Wide Mode: Diameter 113 mm, H 72 mm	Diameter 170 mm/ H135 mm (0.090 mm – 0.500 mm) Diameter 170 mm/ H110 mm (0.090 mm – 0.500 mm) Diameter 170 mm/ H60 mm (0.090 mm – 0.500 mm) Diameter 100 mm/ H100 mm (0.090 mm – 0.500 mm) Diameter 80 mm/	Diameter x Height 8 cm x 8 cm 16 cm x 4 cm 16 cm x 6 cm 16 cm x 8 cm 16 cm x 10 cm 16 cm x 11 cm 16 cm x 13 cm 23 cm x 17 cm (3D ceph) Voxel size: 0.125, 0.2, 0.25, 0.3, 0.4mm

Device	Subject Device	Predicate device		
	PreXion3D Excelsior	**PREXION 3D ECLIPSE (K122199)**	**CS 9300 and CS 9300C (K103659)**	**i-CAT FLX Cone Beam 3D and 2D Panoramic Dental Imaging System (K133620)**
			H80 mm (0.090 mm – 0.500 mm) Diameter 100 mm/ H50 mm (0.090 mm – 0.500 mm) Diameter 50 mm/ H50 mm (0.090 mm – 0.500 mm)	
Volume Size	512x512x512 1024x1024x800	512x512x512	250 x 250 x 250 267 x 267 x 267 339 x 339 x 220 567 x 567 x 367-450 850 x 850 x 300	320x320x288 536x536x443 768x768x288
Dose Level (CTDIw)	Standard (110KV, 3.3mA, 12.8s) 10cm: 2.9mGy 5cm: 1.9mGy Rapid (110KV, 2.1mA, 6.9s) 10cm: 0.9mGy 5cm: 0.8mGy High Resolution (110KV, 3.6mA, 25.6s) 10cm: 4.9mGy 5cm: 3.2mGy High Contrast (110KV, 2.1mA, 25.6s) 10cm: 8.7mGy 5cm: 5.7mGy Standard Child (95KV, 2.2mA, 12.8s) 10cm: 1.4mGy 5cm: 1.0mGy Rapid Child	High Definition (90KV, 4mA, 8.7s) 8cm: 4.57mGy Ultra High Definition (90KV, 4mA, 17.4s) 8cm: 9.32mGy Wide (90KV, 4mA, 9.1s x 2) 11cm: 6.67mGy Light (90KV, 2.6mA, 8.7s) 8cm: 3.01mGy	90KV, 6.3mA, 12sec, 8cm x 8cm: 4.31mGy 90KV, 6.3mA, 12sec, 5cm x 5cm: 3.70mGy 90KV, 6.3mA, 20sec, 5cm x 5cm: 6.46mGy	3D Ceph (120KV, 5mA, 8.9s) 13cm: 1.9mGy*, 11cm: 1.9mGy*, 10cm: 1.9mGy*, 8cm: 2.0mGy*, 6cm: 2.0mGy*, 4cm: 2.1mGy* Quick Scan (120KV, 5mA, 4.8s) 13cm: 1.0mGy*, 11cm: 1.0mGy*, 10cm: 1.0mGy*, 8cm: 1.0mGy*, 6cm: 1.0mGy*, 4cm 1.6mGy*: Quick Scan+ (90KV, 3mA, 4.8s) 13cm: 0.3mGy*, 11cm: 0.3mGy*, 10cm: 0.3mGy*, 8cm: 0.3mGy*, 6cm: 0.3mGy*, 4cm: 0.3mGy* HD (120KV, 5mA,

Device	Subject Device	Predicate device		
	PreXion3D Excelsior	**PREXION 3D ECLIPSE (K122199)**	**CS 9300 and CS 9300C (K103659)**	**i-CAT FLX Cone Beam 3D and 2D Panoramic Dental Imaging System (K133620)**
	(95KV, 1.6mA, 6.9s) 10cm: 0.5mGy 5cm: 0.4mGy			26.9s) 13cm: 3.8mGy*, 11cm: 3.9mGy*, 10cm: 3.6mGy*, 8cm: 4.0mGy*, 6cm: 4.0mGy*, 4cm: 4.2mGy* Quick Scan HD (120KV, 5mA, 14.7s) 13cm: 2.1mGy*, 11cm: 2.1mGy*, 10cm: 2.0mGy*, 8cm: 2.1mGy*, 6cm: 2.1mGy*, 4cm: 2.2mGy* * the sum of 1/3 of the phantom central dose and 2/3 of the peripheral dose.
Performance Standards	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 62366 IEC 62304 IEC 60601-2-63 IEC 61223-3-4 IEC 61223-3-5 IEC 60825-1 ISO 14971 NEMA PS 3.1 - 3.20 ISO 10993-1 ISO 10993-5 ISO 10993-10	UL 60601-1 IEC 60601-1-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-2-7 IEC 60601-2-28 IEC 60601-2-32 IEC 60825-1 IEC 61233-3-4 IEC 61223-3-5 IEC 62304 ISO 14971 NEMA PS 3.1 - 3.20	Unknown	IEC 60601-1: 2005 IEC 60601-1-6:2010 IEC 62366:2007 IEC 60601-2-63:2012 IEC 60601-1-2: 2007 ISO 10993-5 ISO 10993-10

5.7 Non-Clinical Performance Data

The subject device has demonstrated conformance to non-clinical performance requirements through evaluation and testing in accordance with the following harmonized standards:

ANSI/AAMI ES60601-1
IEC 60601-1-2
IEC 60601-1-3
IEC 60601-1-6
IEC 62366
IEC 62304
IEC 60601-2-63
IEC 61223-3-4
IEC 61223-3-5
IEC 60825-1
ISO 14971
NEMA PS 3.1 - 3.20
ISO 10993-1
ISO 10993-5
ISO 10993-10

In addition to the conformance with the above recognized standards, the following testing and non-clinical considerations were preformed:

- Testing for 3D imaging performance to assess MTF for three image orientations (x, y, z) for the applicable 3D modes of device operation.
- Non-clinical considerations according to FDA Guidance "*Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices*"

Results of all non-clinical testing and non-clinical considerations support the safety and effectiveness of the subject device.

5.8 Clinical Performance Data

Clinical considerations according to FDA Guidance "*Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices*" were performed by the qualified clinical assessors. Results of the clinical consideration support the safety and effectiveness of the subject device.

5.9 Conclusions

The subject device has the same intended use/Indications for use as the predicate devices. The subject and predicate devices also share similar technological characteristics such as specifications of X-ray Generation Device, X-ray Image Capturing Device and Scanner, Imaging Mode (i-CAT does not have a Cephalometric imaging mode), Scan Mode and conformance with Performance Standards. The subject and predicate devices also have differences in technological characteristics, such as Tube Voltage, Pulse Exposure, Tube Current, Focal Spot Size, Pixel Size, Pixel Number, Size of Area Receiving X-ray, Detector, Number of Bits, Scanner SID/SOD, Panoramic Scan Performance (Scan Time), Cephalometric Radiography (Scan Time), CT Scan Time, FOV (Voxel Size), Volume Size, Dose Level (CTDIw) and Performance Standards.

We conducted non-clinical and clinical performance testing as follows:

- Conformance with the harmonized standards
- Testing for 3D imaging performance to assess MTF for the three image orientations
- Non-clinical and Clinical considerations according to FDA Guidance "*Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices*"

Based on the above information and all data provided in this submission, the comparison of intended uses, technological characteristics, and non-clinical performance data and clinical performance data demonstrates that the subject device is substantially equivalent to the legally marketed devices identified in this submission.