August 17, 2018

PreXion Corporation
% Mr. Katsumi Hayashi
Director, Quality Assurance and Regulatory Division
1-14-1 Kandasuda-cho,
Chiyoda-ku, Tokyo 101-0041
JAPAN

Re: K181983
Trade/Device Name: PreXion 3D Excelsior
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: July 23, 2018
Received: July 25, 2018

Dear Mr. Hayashi:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181983

Device Name

PreXion 3D 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 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.

(Note: We have added technical term "dental(oral)" to clarify Indications for Use. We believe that is same definition of Indications for Use between predicate device and subject device.)

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.

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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: _____

6.1 Applicant Information

Date Prepared:	July 23th, 2018
Company Name and Address:	PreXion Corporation 1-14-1 Kandasuda-cho, Chiyoda-ku Tokyo, 101-0041 Japan
Contact Person:	Mr. Katsumi Hayashi Director, Quality Assurance and Regulatory Division Phone: +81-3-5297-7551 FAX: +81-3-5297-7552 Email: hayashi@prexion.co.jp

6.2 Device Information

Type of 510(k) Submission	Special
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

6.3 Predicate Device Information

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

510(k) Number:	K173878
Applicant:	PreXion Corporation
Device Name:	PreXion 3D Excelsior
Regulation Number:	21 CFR 892.1750
Product Code:	OAS
Device Class:	II

6.4 Device Description

PreXion 3D 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.

Summary of predicate device modifications
Predicate device has Panoramic scan mode, but Subject device is added CT-panoramic mode besides Panoramic scan mode. CT-panoramic mode is a function for CT imaging in which a panoramic image is produced by performing panoramic image reconstruction using the raw-data from CT scan. The user can observe CT image and CT-panoramic image at the same time.
Furthermore, Subject device is added Airway measurement function, which gives inner wall of airway distinguish color, and it calculates volume and cross section area.

6.5 Intended Use/Indications for Use

PreXion 3D Excelsior is intended to produce two dimensional digital 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.

6.6 Comparison to the Predicate Device

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

Device	**Predicate Device**	**Modified Device**
	PreXion3D Excelsior (K17387)	**PreXion3D Excelsior**
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.	PreXion3D Excelsior is intended to produce two dimensional digital 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

		Cephalometric imaging also includes the hand and wrist to obtain carpus images for growth and maturity assessment	the hand and wrist to obtain carpus images for growth and maturity assessment
X-ray Generation Device	Tube Voltage	60-110KV	60-110KV
	Pulse Exposure function	Yes	Yes
	Tube Current	1-6mA	1-6mA
	Focal Spot Size	0.3mm	0.3mm
X-ray Image Capturing Device	Detector	125μm x 125μm, 125μm x 250μm (CT) 125μm x 125μm (Panoramic) 140 μm x 140μm (Ceph)	125μm x 125μm, 125μm x 250μm (CT) 125μm x 125μm (Panoramic) 140 μm x 140μm (Ceph)
	Pixel Number	1280x1024 (CT) 128x1280 (Panoramic) 2112x1754 (Cephalometric)	1280x1024 (CT) 128x1280 (Panoramic) 2112x1754 (Cephalometric)
	Size of Area Receiving X-ray	160mm x 128mm (CT) 160mm x 12.5mm (Panoramic) 295.68 x 245.56mm (Ceph)	160mm x 128mm (CT) 160mm x 12.5mm (Panoramic) 295.68 x 245.56mm (Ceph)
	Number of Bits	16bits (CT, Panorama) 14bits (Ceph)	16bits (CT, Panorama) 14bits (Ceph)
Scanner	SID/SOD	700mm/ 470mm (CT,Panoramic) 1735mm / 1500mm (Ceph)	700mm/ 470mm (CT, Panoramic) 1735mm / 1500mm (Ceph)
	Dimension (WxDxH)	930 mm x 1230 mm x 2220 mm (CT, Panoramic) 1816 mm x 1230 mm x 2220 mm (with Ceph)	930 mm x 1230 mm x 2220 mm (CT, Panoramic) 1816 mm x 1230 mm x 2220 mm (with Ceph)
	Weight	165 kg (CT, Panoramic) 200kg (Ceph)	165 kg (CT, Panoramic) 200kg (Ceph)
Imaging Mode		CT scan, Panoramic scan, Cephalometric radiography	CT scan, Panoramic scan, Cephalometric radiography

Panoramic Scan Performance (Scan Time)	8-16sec	8-16sec
Cephalometric Radiography (Scan Time)	0.5-0.8 sec	0.5-0.8 sec
Viewer Software (Image Analysis System Software)	Display High-resolution 2D and 3D Images Function Image Processing Function Image Operation Function Output Function	Display High-resolution 2D and 3D Images Function Image Processing Function Image Operation Function Including Airway measurement Output Function
Console Software System Settings	CT Scan	CT Scan including CT-Panoramic mode

Modified device is added CT-Panoramic mode and Airway measurement function.
CT-panoramic mode is a function for CT imaging in which a panoramic image is produced by performing panoramic image reconstruction using the raw-data from CT scan. The user can observe CT image and CT-panoramic image at the same time.
Airway measurement function gives inner wall of airway distinguish color, and it calculates volume and cross section area.

6.7 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.

6.8 Brief description of software quality activities

Software quality activities for subject device is according to above standards. Based on risk management and usability evaluation, the software is verified and validated including bench tests and user evaluations. Via these processes, software quality activities for subject device comply with software moderate level concern.

6.9 Conclusions

The subject device clarified the Intended Use/Indications for Use, but both Intended Use/Indications for Use are same meaning between predicate and subject devices. In Viewer Software, the subject device has a different function from those of the predicate device. But, this is just additional supplemental function of the image processing functions. In Console Software, the subject device has different function from those of the predicate device. But, this is just additional supplemental function of the CT Scan mode.

Based on the above information and all data provided in this submission, the comparison of Intended Uses/Indications for Use and technological characteristics that the subject device is substantially equivalent to the predicate device identified in this submission.