September 8, 2023

PreXion Corporation
℅ Mr. Kenji Tanaka
Manager
1-14-1, Kandasuda-cho
Chiyoda-ku, Tokyo 101-0041
JAPAN

Re: K232166
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: July 21, 2023
Received: July 21, 2023

Dear Mr. 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,

Lu Jiang

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

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.

Submission Number *(if known)*

K232166

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.

K232166 510(k) Summary

Prepared on: 2023-09-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	PreXion Corporation
Applicant Address	1-14-1, Kandasuda-cho Chiyoda-ku Tokyo 101-0041 Japan
Applicant Contact Telephone	+81-3-5297-7553
Applicant Contact	Mr. Kenji Tanaka
Applicant Contact Email	px-ra@prexion.co.jp

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	PreXion3D Expedition
Common Name	X-ray, Tomography, Computed, Dental
Classification Name	Computed tomography x-ray system
Regulation Number	21 CFR 892.1750
Product Code	OAS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222150	PreXion3D Expedition	OAS

Device Description Summary

21 CFR 807.92(a)(4)

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 crosssection 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).

<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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The device has the same indications for use in comparison to the predicate device(PreXion3D Expedition/P04A). The subject device of PreXion3D Expedition 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.
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.

Technological Comparison

21 CFR 807.92(a)(6)

The different technological characteristics are summarized in the following three points. The difference is in the FPD, part of the software, and the maximum X-ray field. First, we have confirmed that there are no problems with the FPD according to SSXI guidance, and the report is available as an attachment to this application. Second, the software only changes the protocol of the interface due to the change in the FPD, and we have confirmed that there are no problems with the operation of this software in the system test. Finally, the maximum X-ray irradiation field has been confirmed in the IEC 60601-2-63 test report. Other than the above, the intended use/ appearance/design/materials/ labeling for precautions and warnings/operating principle/energy source/manufacturer, etc. are all the same. Based on these points, we claim the substantial equivalence of this device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

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 nonclinical 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 to support substantial equivalence of the subject 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,AMD1:2020 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-Offthe-Shelf-(OTS)-Software---Guidance-for-Industry", "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"

We conducted the clinical image validation and as a result, it was confirmed that they are clinically anatomically valid.

The results of the above non-clinical and clinical studies indicate that the device is substantially equivalent to the predicate device in safety, efficacy, and performance.