PreXion Corporation
% Hiroaki Takahashi
General Manager, Quality Assurance &
Regulatory Division
1-14-1, Kanda Suda-cho
Chiyoda-ku, Tokyo 101-0041
JAPAN

April 9, 2020

Re: K193329
Trade/Device Name: PreXion3D Explorer EX
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: March 16, 2020
Received: March 19, 2020

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193329

Device Name
PreXion3D Explorer EX

Indications for Use *(Describe)*
PreXion3D Explorer EX is intended to produce two-dimensional digital x-ray images including panoramic 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.

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. Use of equipment and exposure settings designed for adults of average size can result in excessive radiation exposure for a smaller patient. Studies have shown that pediatric patients may be more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher), and so unnecessary radiation exposure is of particular concern for pediatric patients.

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

Device Name: PreXion3D Explorer EX

K193329

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

November 29th, 2019

4. Device Identification

Product/Trade Name:	PreXion3D Explorer EX
Common Name:	Computed Tomography X-ray System
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	OAS

5. Legally Marketed Predicate Device(s) and Reference Device

Predicate Device:

Product/Trade Name:	PreXion3D Explorer
510(K) Number:	K190320
Common Name:	Computed Tomography X-ray System
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	OAS

Reference Device:

Product/Trade Name:	PreXion3D Excelsior
510(K) Number:	K181983
Common Name:	Computed Tomography X-ray System
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	OAS

6. Indication for Use Statement

PreXion3D Explorer EX is intended to produce two-dimensional digital x-ray images including panoramic 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.

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. Use of equipment and exposure settings designed for adults of average size can result in excessive radiation exposure for a smaller patient. Studies have shown that pediatric patients may be more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher), and so unnecessary radiation exposure is of particular concern for pediatric patients.

7. Device Description

<Summary of Predicate Device (PreXion3D Explorer)>

PreXion3D Explorer (Predicate Device) 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 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, CT-Panoramic scan) and Cephalometric Scan

<Summary of Modification>

The Primary intention of this Traditional 510(k) submission is to reflect the customers' voice (which does not affect to product safety and performance) to the predicate device and to expand the line-up of PreXion3D Explorer Family.

Modifications:

1. To apply Chinrest/Forehead Holder which are used in PreXion3D Excelsior (K181983)
2. To add a touch panel and a mirror for ease of use which is used in PreXion3D Excelsior (K181983)
3. To modify middle size FOV: From "15 x 8" to "15 x 10"
4. To add middle size FOV: 10 x 10
5. To add Panoramic Scan Function which is used in PreXion3D Excelsior (K181983)
6. To change detector's effective area (smaller by 1.5mm due to vendor design change)
7. To disable Cephalometric Scan Function by replacing the console software. The console software is modified to do so.

As "Table-6A: Comparison of Characteristics" shows that PreXion3D Explorer EX (Device in concern) is the equivalent with the predicate device, PreXion3D Explorer (K190320), and it appears to be PreXion3D Explorer without Cephalometric Scan Function.

<Summary of Device Description in Concern>

PreXion3D Explorer EX 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 EX 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) and the tomographic image (CT scan, CT-Panoramic scan, Panoramic Scan).

8. Substantial Equivalence Discussion

The following table compares the PreXion3D Explorer EX 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-6A: Comparison of Characteristics

	Subject Device	**Predicate Device**	**Reference Device**	**Comparison to Predicate**
Manufacturer	**PreXion Corporation**	**PreXion Corporation**	**PreXion Corporation**	
Trade Name	**PreXion3D Explorer EX**	**PreXion3D Explorer**	**PreXion3D Excelsior**	
510(k) Number	K193329/S001	K190320	K181983	N/A
Product Code	OAS	OAS	OAS	Same
Regulation Number	OAS: 21 CFR 892.1750	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	OAS: Computed tomography x-ray system	Same
Device Classification Name	X-Ray, Tomography, Computed, Dental	X-Ray, Tomography, Computed, Dental	X-Ray, Tomography, Computed, Dental	Same
Indications for use:	PreXion3D Explorer EX is intended to produce two-dimensional digital x-ray images including panoramic 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. 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	PreXion3D Explorer 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.	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	Cephalometric Scan Function is disabled by the console software. Otherwise equivalent

		weight measurements approximately correspond to that of an average 5 year-old. Use of equipment and exposure settings designed for adults of average size can result in excessive radiation exposure for a smaller patient. Studies have shown that pediatric patients may be more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher), and so unnecessary radiation exposure is of particular concern for pediatric patients.			
Patient/User Characteristics					
Target Population		Children aged 6 (except infants) to elderly	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	The dental, oral, maxillofacial region ENT (Ear, Nose and Throat) and neck region	Same
Users		Health care professionals	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	CHINREST: polycarbonate HEADREST: carbon BELT: polyvinyl chloride	CHIN REST: polycarbonate Forehead Holder: silicone rubber HANDLE GRIP: silicone rubber	Same materials are used
Sterility		Non-sterile	Non-sterile	Non-sterile	Same
X-ray Generation Device	**Tube Voltage**	90-110KV	90-110KV	60-110KV	Same or Equivalent
	Pulse Exposure function	Yes	Yes	Yes	Same
	Tube Current	1-5mA	1-3mA	1-6mA	Tube Current is similar. Added according with Panoramic Scan.

	Focal Spot Size	0.3mm x 0.3mm	0.3mm x 0.3mm	0.3mm x 0.3mm	Same
X-ray Image Capturing Device	**Detector**	FPD (TFT)	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)	248 µm x248µm (With binning) (CT, CT-Panoramic, Ceph) 124 µm x124µm (Without binning) (CT, CT-Panoramic, Ceph)	250 µm x250µm (With binning) (CT, CT-Panoramic, Panoramic) 125 µm x125µm (Without binning) (CT, CT-Panoramic) 125µm x 125µm (Panoramic) 140 µm x 140µm (Ceph)	Equivalent
	Pixel Number	1024x1280(With binning) (CT, CT-Panoramic) 2560x2048(Without binning) (CT, CT-Panoramic) 1900 x 120 (Panoramic)	1024x1280(With binning) (CT, CT-Panoramic) 2560x2048(Without binning) (CT, CT-Panoramic, Ceph) 1024x1280(With binning)	1024x1280 (CT) 128x128 (Panoramic) 2112x1754 (Cephalometric)	Comparing to K190320, Device is same, just the use is changed so that Ceph is disabled and Panoramic Scan is added.
	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, Ceph)	160mm x 128mm (CT) 160mm x 12.5mm (Panoramic) 295.68 x 245.56mm (Ceph)	
	Number of Bits	16bits (CT, CT-Panoramic, Panoramic)	16bits (CT, CT-Panoramic, Ceph)	16bits (CT, CT-Panoramic, Panoramic) 14bits (Ceph)	
Scanner	**SID/SOD**	700mm/ 420mm (CT, CT-Panoramic, Panoramic)	700mm/ 420mm (CT, CT-Panoramic, Ceph)	700mm/ 470mm (CT, Panoramic) 1735mm / 1500mm (Ceph)	Comparing to K190320, geometry is same
	Dimension (WxDxH)	880 mm x 1237 mm x 2268 mm (CT, CT-Panoramic, Panoramic)	880 mm x 1237 mm x 2268 mm (CT, CT-Panoramic, Ceph)	930 mm x 1230 mm x 2220 mm (CT, CT-Panoramic, Panoramic) 1816 mm x 1230 mm x	

				2220 mm (with Ceph)	
	Weight	185 kg (CT, CT-Panoramic, Panoramic)	165 kg (CT, Panoramic, Ceph)	165 kg (CT, Panoramic) 200kg (Ceph)	Similar
Imaging Mode		CT scan, CT-Panoramic, Panoramic scan	CT scan, CT-Panoramic, Cephalometric radiography	CT scan, CT-Panoramic, Panoramic scan, Cephalometric radiography	No Cephalometric Radiography Added Panoramic scan (Identical to K181983)
Panoramic Scan Performance (Scan Time)		8-16sec	18sec	8-16sec	Scan Time is improved or same.
Cephalometric Radiography (Scan Time)		N/A	0.16 sec	0.5-0.8 sec	No Cephalometric Radiography
CT Scan Performance	**Scan Time**	10-20sec	10-20sec	5.2-23.6sec	Same or Similar
	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 H78mm (0.100 - 0.200mm) Diameter 50mm x H50mm (0.100 - 0.200mm)	Diameter 150mm x H130mm (0.100 - 0.200mm) Diameter 150mm x H81 (0.200mm) Diameter 100mm x H81mm (0.100 - 0.200mm) Diameter 100mm x H50mm (0.100 - 0.200mm) Diameter 50mm x H50mm (0.100 - 0.200mm)	Added one middle size FOV and gets bigger in middle size FOV for user requirement.
Spatial Resolution		Standard mode: 50%MTF: 0.95LP/mm 20%MTF:2.0LP/mm Rapid Mode: 50%MTF: 0.95LP/mm 20%MTF:2.0LP/mm High Resolution mode:	Standard mode: 50%MTF: 0.95LP/mm 20%MTF:2.0LP/mm Rapid Mode: 50%MTF: 0.95LP/mm 20%MTF:2.0LP/mm High Resolution mode:	Standard mode 50%MTF: 1.2LP/mm 20%MTF:2.3LP/mm Rapid Mode 50%MTF: 1.2LP/mm 20%MTF:2.3LP/mm High Resolution mode:	Same or equivalent

	50%MTF: 0.95LP/mm 20%MTF:2.0LP/mm High contrast mode: 50%MTF: 0.95LP/mm 20%MTF:2.0LP/mm	50%MTF: 0.95LP/mm 20%MTF:2.0LP/mm High contrast mode: 50%MTF: 0.95LP/mm 20%MTF:2.0LP/mm	50%MTF: 1.2LP/mm 20%MTF:2.3LP/mm High contrast mode: 50%MTF: 1.2LP/mm 20%MTF:2.3LP/mm	
Viewer Software (Image Analysis System Software)	Display High-resolution 2D and 3D Images Function Image Processing Function includes Airway measurement Image Operation Function Output Function	Display High-resolution 2D and 3D Images Function Image Processing Function include Airway measurement Image Operation Function Output Function	Display High-resolution 2D and 3D Images Function Image Processing Function include Airway measurement Image Operation Function Output Function	Same
Console Software System Settings	CT Scan include CT-Panoramic mode	CT Scan include CT-Panoramic mode	CT Scan include CT-Panoramic mode	Same
Applied Standard				
Electrical Safety Standard **Electromagnetic Compatibility Standard** **Radiation Safety Standard** **Electrical Equipment Usability Safety Standard** **Usability Engineering Standard** **Software Lifecycle Process Standard** **Essential performance of dental extra-oral X-ray equipment Standard** **Acceptance tests of Imaging performance of dental X-ray equipment Standard** **Acceptance tests of Imaging performance of computed tomography X-ray equipment Standard**	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 62366 -1 IEC 62304 IEC 60601-2-63 IEC 61223-3-4 IEC 61223-3-5	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	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	Same

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

9. Non-Clinical Performance Data

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

Summary of performance testing performed for each modification stated in Section 7:

1. To apply Chinrest/Forehead Holder which are used in PreXion3D Excelsior (K181983)

   The biocompatibility is safe because same materials as to marketed device are used.

2. To add a touch panel and a mirror for ease of use which is used in PreXion3D Excelsior (K181983)

   IEC60601-1 test was performed by the outside test lab qualified with ISO17025. Regarding added mirror, risk management was performed and decided it's acceptable.

3. To modify middle size FOV: From "15 x 8" to "15 x 10"

   System test was performed to confirm that 15 x 10 of middle size FOV is valid.

4. To add middle size FOV: 10 x 10

   System test was performed to confirm that 10 x 10 of middle size FOV is valid.

5. To add Panoramic Scan Function which is used in PreXion3D Excelsior (K181983)

   Imaging performance test was performed and has confirmed to comply with IEC61223-3-4.

6. To change detector's effective area (smaller by 1.5mm due to vendor design change)

   An American board-certified radiologist has confirmed that images with the modification as a change to the detector's effective area is of diagnostic quality.

7. To disable Cephalometric Scan Function by replacing the console software. The console software is modified to do so.

System test was performed to confirm that system is valid including the function of disabling Cephalometric Scan Function.

The PreXion3D Explorer EX 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 ABSI/AAMI ES 60601-1, IEC 60601-1-3 and IEC 60601-1-6
- Electromagnetic Safety testing per IEC 60601-1-2
- Dental extra-oral X-ray equipment testing per IEC 60601-2-63
- Acceptance testing of X-ray equipment per IEC 61223-3-4 and IEC 61223-3-5
- Laser safety testing per IEC 60825-1
- DICOM testing per NEMA PS 3.1 - 3.20
- Usability testing per IEC 62366-1
- Software verification and validation per IEC 62304
- Storage and Transport Testing per ISO 4180
- 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. Cybersecurity Activities

We make post-market Cybersecurity actions as follows:

1. Collect cybersecurity information from the link described in Post-market Plan

   As of October, 2019, there is no cyber security thread by PreXion's investigation.

2. Collect information if there is any cyber security breach at customer site.

   As of November 11th, 2019, six PreXion3D Explorer (Predicate Device) have been installed in the US and no cyber breach is reported by the customer.

12. 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 EX, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.