DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Imaging Sciences International
% Ms. Ruth Pui
Regulatory Affairs Manager
1910 North Penn Road
HATFIELD PA 19440

November 10, 2016

Re: K162085
Trade/Device Name: i-CAT FLX V series / KaVo 3D eXam+ V series
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: October 25, 2016
Received: October 26, 2016

Dear Ms. Pui:

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)*

K162085

Device Name
Cone Beam 3D and 2D Panoramic Dental Imaging System
(i-CAT FLX V series/ KaVo 3D eXam+ V series)

Indications for Use *(Describe)*

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, which includes ENT and maxillofacial areas (such as TM Joint studies, mandible & maxilla for implant planning, sinuses, airway), 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.

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
for
i-CAT FLX V Series / KaVo 3D eXam+ V Series

1. Submitter Information**:**

Imaging Sciences International,
also dba DEXIS, Gendex Dental Systems
1910 North Penn Road,
Hatfield, PA 19440
Phone: 215-997-5666; Fax: 215-997-5665

Contact Person: Ruth Pui
Title: Regulatory Affairs Manager
Direct Phone No.: (267) 954-1479

Date Prepared: October 25, 2016

2. Device Name:

Proprietary Name: i-CAT FLX V series / KaVo 3D eXam+ V series
Common Name: X-ray, Tomography, Computed, Dental
Classification Name: Computed tomography x-ray system
CFR Number: 892.1750
Device Class: II
Product Code: OAS

3. Predicate Devices:

Proprietary Name: GALILEOS family
510(k) Number K123070
Common Name: X-ray, Tomography, Computed, Dental
Classification Name: Computed tomography x-ray system
CFR Number: 892.1750
Device Class: II
Product Code: OAS

Proprietary Name: i-CAT FLX
510(k) Number K133620
Common Name: X-ray, Tomography, Computed, Dental
Classification Name: Computed tomography x-ray system
CFR Number: 892.1750
Device Class: II
Product Code: OAS

4. Description of Device:

i-CAT FLX V series / KaVo 3D eXam+ V series manufactured by Imaging Sciences International, is a Cone Beam Volumetric Tomography and Panoramic X-ray dental imaging system that consists of a scanner and a software package for image reconstruction. The two models, i-CAT FLX / KaVo 3D eXam+, are of identical design in the i-CAT Scanner family. The components of the system include the main affixed unit, the overhead, the gantry, the tube head, the X-ray source assembly and collimator, the receptor panel, and software package for image reconstruction. The system is an open design that allows patients to sit upright during a procedure. An electric powered seat is built into the scanner for proper patient positioning. The V series refer to 3 different field-of-view configurations (V8, V10, V17) available on each model based on licensing of the acquisition software.

The software package includes a device specific software package (SmartScan STUDIO) that is required to operate the i-CAT FLX System through a visual touchscreen interface and a post-processing imaging software. The modules within the device specific software perform the Image Acquisition, Quality Assurance, Device Calibration, and Image Reconstruction and Processing functionalities of the device. The software utilizes a modified Feldkamp algorithm for reconstruction. There is a basic DICOM viewer component (with limited image viewing capabilities) for the operator to ensure that the data collection and image processing are correct. Also provided with the device is a post-processing imaging software, such as TxSTUDIO marketed under K123519. It is a volumetric imaging software designed specifically for dental clinicians, intended for use as a planning and simulation software in the placement of dental implants, orthodontics and surgical treatment. The imaging software reads DICOM data from dental CT machines, such as devices in the i-CAT family.

Cone Beam Volumetric Tomography is a medical imaging technique that uses X-rays to obtain cross-sectional images of the head or neck. The proposed device is a CBCT dental system with 2 modes of operation: panoramic and CBCT. The X-ray incident upon the receptor that generate sufficiently contrasted images. Quality of the images depends on the level and amount of X-ray energy delivered to the tissue. When interpreted by a trained physician, these images provide useful diagnostic information. The scanner has the ability to capture data for 3D skull reconstruction for the following procedures:

- CBCT mode:
  - Implants
  - TM Joints
  - Reconstructed Panoramic
  - Reconstructed Cephalometrics
  - Airway / Sinus, etc.
  - Nerve Canal
- Panoramic mode:
  - PAN - Conventional Digital Panoramic Feature

In addition, the user can choose to scan using the Standard protocol, the QuickScan protocol, or the QuickScan+ protocol. The user can choose to reduce the radiation exposure to patients by lowering the exposure time (from Standard to QuickScan), or by lowering all the loading factors (from Standard to QuickScan+). The radiation dose level, in the form of DAP value, is readily displayed on the protocol selection screen of the user interface so the user may make an informed choice.

5. Indications for Use:

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, which includes ENT and maxillofacial areas (such as TM Joint studies, mandible & maxilla for implant planning, sinuses, airway), 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.

The proposed indications for use above of i-CAT FLX / KaVo 3D eXam+ include specification of airway within the ENT and maxillofacial area. The proposed device has been verified and validated to satisfy the requirements derived from the indications for use.

6. Summary of Technological Characteristics:

i-CAT FLX / KaVo 3D eXam+ models share the same architectural components as the predicate devices including:

a. An X-ray source on a motorized gantry
b. Collimation of X-ray
c. Two-dimensional (2D) X-ray detector (for Panoramic and Cone Beam mode)
d. A patient positioning and support system to ensure stability of the patient during scan.
e. A software package which prepares and displays three dimensional (3D) reconstructions of the acquired data.

The system architecture of the proposed device is identical to the predicate device, i-CAT FLX (K133620), see comparison table below for details.

Comparison Table:

Characteristics	**Proposed Device i-CAT FLX / KaVo 3D eXam+ V series**	**Predicate Device GALILEOS Comfort Plus (K123070)**	**Predicate Device i-CAT FLX (K133620)**
Principle of Operation	Cone Beam X-ray	Cone Beam X-ray	Cone Beam X-ray
Generator	High Frequency, Constant Potential	N/A	High Frequency, Constant Potential
X-ray tube	Stationary anode	Stationary Anode	Stationary anode

Characteristics	Proposed Device i-CAT FLX / KaVo 3D eXam+ V series	Predicate Device GALILEOS Comfort Plus (K123070)	Predicate Device i-CAT FLX (K133620)
Tube Voltage	120 kV(peak)	98 kV	120 kV(peak)
Tube Current	3-7 mA	3-6 mA	3-7 mA
Scan time	4 to 40 seconds	14 seconds	4 to 40 seconds
Exposure	6-100mAs	30 mAs	6-100mAs
Target material	Tungsten	Tungsten	Tungsten
Minimum Filtration	> 10 mm of Al equivalent at 120 kV	2.8 mm of Al equivalent at 98 kV	> 10 mm of Al equivalent at 120 kV
Focal spot	0.5 mm	0.5 mm	0.5 mm
Anode capacity	30 kHU	48 kHU	30 kHU
Detector*			
Type	Amorphous Silicon	Image Intensifier	Amorphous Silicon
Conversion Screen	Direct Deposit CsI, DRZ Plus	Not Available	Direct Deposit CsI, DRZ Plus
Size	20 x 25 cm	Not Available	20 x 25 cm
Active Input Window Size	N/A	215 mm diameter	N/A
Camera	N/A	Pixels: 1000^2, FPS: 15-30, Dynamics: 12 bits, (4096 brightness values), 63 dB	N/A
Total Pixel Area	19.5 x 24.4 cm	Not Available	19.5 x 24.4 cm
Pixel Matrix	1536 x 1920	Not Available	1536 x 1920
Pixel Pitch	127 μm^2	Not Available	127 μm^2
Limiting Resolution	3.94 lp/mm	Not Available	3.94 lp/mm
MTF	>48% @ 1 lp/mm	Not Available	>48% @ 1 lp/mm
DQE	>75% (1x1)	Not Available	>75% (1x1)
Energy Range	40 – 160 kVp	Not Available	40 – 160 kVp
Gantry			
Resolution angle / Orbital angle	360°	204°	360°
Number of projections/ single exposures	160, 300, 320, 600, 1100 or 1200	200, 357	160, 300, 320, 600, 1100 or 1200
Orientation	Vertical	N/A	Vertical
Source to Sensor distance	71.4 cm	59.0 cm	71.4 cm

Characteristics	Proposed Device i-CAT FLX / KaVo 3D eXam+ V series	Predicate Device GALILEOS Comfort Plus (K123070)	Predicate Device i-CAT FLX (K133620)
Source to isocenter distance	49.53 cm	41.3 cm	49.53 cm
Image Reconstruction			
Field of view, axial	17 cm max	15.4 cm (diameter) spherical imaging volume	17 cm max
Field of view, cross sectional	23 cm max		23 cm max
Other			
Effective Dose (ICRP 2007)	4-171 µSv (Ludlow)	28-154µSv (Ludlow)	4-171 µSv (Ludlow)
Workstation	Intel based PC	Intel based PC	Intel based PC
Electrical requirements	100VAC, 115VAC, 200VAC or 230VAC 50/60 Hz (Factory Set)	200 V – 240 V, 50/60 Hz	100VAC, 115VAC, 200VAC or 230VAC 50/60 Hz (Factory Set)
Patient Positioning	Seated	Standing or seated	Seated
Patient Positioning Accessories	Chin rest, chin cup, bite block, head rest, head strap, head holder, booster seat, foot stool	Chin rest, bite block, forehead support and head fixation device	Chin rest, chin cup, bite block, head rest, head strap, head holder, booster seat, foot stool
Laser indication of scanned area	Yes	Yes	Yes
Exposure parameters for determining leakage radiation	7mA / 120 kV	6mA / 98 kV	7mA / 120 kV
Continuing current for leakage radiation measurements	0.5 mA (at 130 kVp)	0.14 mA	0.5 mA (at 130 kVp)
Performance-related Conformance Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-63 IEC 62366	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-2-63	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-63 IEC 62366

*Receptor panels utilized in the proposed device has been previously cleared as a component of the device in K133620.

As evidenced through the Design Verification and Validation, the proposed device can produce volumetric and panoramic images of the maxillofacial (including ENT) areas in the head, and they are of equivalent diagnostic quality as the predicate devices. The minor technological difference in the shape of image volumes does not affect imaging of the intended anatomical structures.

Based upon an analysis of the technological differences, and the substantiation through design verification and validation, ISI determines that the proposed i-CAT FLX / KaVo 3D eXam+ is substantially equivalent to the predicate devices, GALILEOS Comfort Plus (K123070) and i-CAT FLX (K133620), and does not raise any new concerns.

7. Non-Clinical Performance Data:

   Performance bench testing was conducted as part of design control to ensure the substantial equivalence of i-CAT FLX/KaVo 3D eXam+ to the predicate devices. The substantial equivalence for the proposed indications for use is substantiated through verification and validation testing on two dimensional images and three dimensional volume reconstructions of the head area, which includes ENT and maxillofacial areas, for use in planning and diagnostic support in adult and pediatric care. The verification and validation activities for the software package also supports the substantial equivalence of the proposed device. Biocompatibility evaluation was conducted on patient contacting accessory parts and found to be in conformance with ISO 10993-5:2009 and ISO 10993-10:2010. EMC and Electrical Safety testing were performed by Intertek Testing Services and found to meet all the requirements in standards IEC 60601-1: 2005 (R)2012 (AAMI ES60601-1:2005/(R)2012), IEC 60601-1-6:2010, IEC 62366:2007/(R)2013, IEC 60601-2-63:2012, IEC 60601-1-3:2008, IEC 60601-1-2:2007, and IEC 60825-1:2007.

8. Clinical Performance Data:
   Clinical images acquired using i-CAT FLX/KaVo 3D eXam+ were reviewed by qualified clinicians to be of acceptable clinical effectiveness for the proposed indications for use.

9. Conclusion as to Substantial Equivalence:
   Based on the substantial equivalence comparison of intended use, design, technological characteristics, performance, labeling, biocompatibility, standards, and other characteristics, the minor differences between i-CAT FLX/KaVo 3D eXam+, and the predicate devices, GALILEOS Comfort Plus (K123070) and i-CAT FLX (K133620), do not raise new concerns for the proposed indications of use. Imaging Sciences International concludes that the proposed device is substantially equivalent to the predicate devices.