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

EDLEN IMAGING LLC
% Mr. Nick Radachi
General Manager
16441 North 91st Street, Suite 102
SCOTTSDALE AZ 85260

June 7, 2016

Re: K151137
Trade/Device Name: X-VIEW, IMAGEN
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS, MUH
Dated: April 21, 2016
Received: April 27, 2016

Dear Mr. Radachi:

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)*
K151137

Device Name
X-VIEW, IMAGEN

Indications for Use *(Describe)*
The X-VIEW, IMAGEN, a panoramic x-ray imaging system with cephalometric capabilities, is an extraoral source x-ray system intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry. It has the capability of using cone beam volumetric technology techniques to generate dento-maxillofacial 3D images. The device uses a cone shaped x-ray beam projected onto a flat panel detector, and the examined volume image is reconstructed to be viewed via 3D viewing stations. 2D Images are obtained using the standard narrow beam technique. The device is to be operated and used by dentists, radiologists and other legally qualified health care professionals.

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

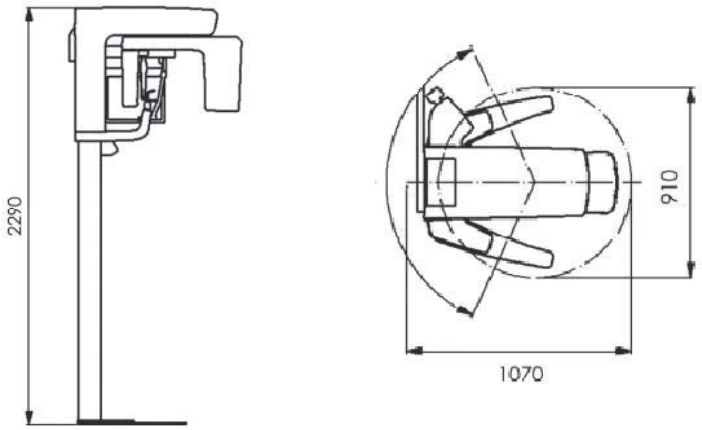
This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 892.1750.

Submitter:	Edlen Imaging LLC 16441 N 91st Street Suite 102 Scottsdale, Arizona USA 85260
Contact Person:	Nick Radachi 480-452- 2939 nick@edlenimaging.com

Date Prepared:	April 22, 2015
Subject Device:	X-VIEW, IMAGEN
Common Name:	Dental CBCT
Classification Name:	Computed Tomography X-ray System
Class:	II
Product Code:	OAS, MUH
Predicate Device:	Planmeca ProMax
Classification Name:	Extraoral source x-ray system
Class:	II
510K Number:	K060328
Product Code:	MUH
Predicate Device:	Papaya 3D Plus
Classification Name:	X-ray, tomography, computed, dental
Class:	II
510K Number:	K150354
Product Code:	OAS
Regulation Number:	21 CFR 892.1750

Product Description

X-VIEW, IMAGEN is a 3-dimensional CBCT system that allows the execution of all commonly used x-rays in both dental and orthodontic fields (excluding intraoral radiographs) and also allows the acquisition of tomographic radiographs, or volumetric 3D. It uses CBCT (Cone Beam Computed Tomography) with a flat panel detector to provide high-definition volumetric images.



The flat panel detector operates via 5 th Generation X-ray CMOS technology. This sensor delivers three times more sensitivity and five times more signal-to-noise performance than other standard technologies of its kind, reducing patient dose in dynamic x-ray imaging modalities like computed tomography. It features a 1300 x 1300 pixel resolution, with 100 um pixel pitch, integrated memory buffer and integrated faraday cage. The detector captures Medium Field of View Cone Beam Computed Tomography images at 30 frames per second, and frame-based panoramic images at 300 frames per second.

All images are acquired by the device and processed via an external PC and imaging software. The device will utilize OnDemand3D (K113543) imaging software to store, manipulate and optimize the images acquired by the X-VIEW, IMAGEN. It is a complete imaging solution used by dentists, researchers and orthodontists. It provides a module-based software that allows DICOM data storage, and includes customizable tools to aid in diagnosis and treatment planning.

Indication for Use

X-VIEW, IMAGEN is an extra-oral source x-ray system intended for dental radiographic examination of the teeth, jaw, and oral structures. It uses Cone Beam Computed Tomography and a flat panel detector to generate 3-dimensional volumetric images that are reconstructed via software. 2D panoramic images can be obtained using a standard narrow-beam technique. The device is to be operated and used by dentists, radiologists and other legally qualified health care professionals.

Rationale for Substantial Equivalence

The X-VIEW, IMAGEN is defined as Substantially Equivalent (SE) to the ProMax3D, manufactured by Planmeca (060328) and the Papaya 3D Plus, manufactured by Genoray. X-VIEW, IMAGEN has the same indication for use as the predicate devices. It shares the same technological characteristics as the predicate devices. Minor technological differences do not raise any new questions regarding safety or effectiveness of the devices. X-VIEW, IMAGEN has the same indication for use as the predicate devices. It performs the same functions based on well-known technology and shares the same technological

characteristics as the predicate devices in identical environments. Minor technological differences do not raise any new questions regarding safety or effectiveness of the devices, so it is as safe and effective as the predicate devices.

The following table compares the X-VIEW, IMAGEN to the predicate devices:

	Edlen Imaging X-VIEW, IMAGEN K151137/S001	Planmeca ProMax 3D K060328	Genoray Papaya 3D Plus K150354
Indications for Use	X-VIEW, IMAGEN is an extra-oral source x-ray system intended for dental radiographic examination of the teeth, jaw, and oral structures. It uses Cone Beam Computed Tomography and a flat panel detector to generate 3-dimensional volumetric images that are reconstructed via software. 2D panoramic images can be obtained using a standard narrow-beam technique. The device is to be operated and used by dentists, radiologists and other legally qualified health care professionals.	Planmeca Promax 3D is a three dimensional Cone Beam Computed Tomographic (CBCT) x-ray system, which is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The device uses cone shaped x-ray beams projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. The device is to be operated and used by dentists and other legally qualified professionals	PAPAYA 3D Plus is a digital panoramic, cephalometric and tomographic extra-oral X-ray system, indicated for use in: (i) producing panoramic X-ray images of the maxillofacial area, for diagnostic examination of dentition (teeth), jaws and oral structures; and (ii) producing radiographs of jaws, parts of the skull and carpus for the purpose of cephalometric examination, when equipped with the cephalometric arm; (iii) producing tomographic images of the oral and maxillofacial structure, for diagnostic examination of dentition(teeth), jaws ,oral structures and some cranial bones if equipped with CBCT option. The system accomplishes tomographic exam by acquiring a 360-degree rotational X-ray sequence of images and reconstructing a three-dimensional matrix of the examined volume, producing two dimensional views of this volume and displaying both two dimensional images and three-dimensional renderings
Generator/Tube			
X-ray Generator	High Frequency	High Frequency	High Frequency

Focal Spot Size (mm)	0.5	0.5	0.5
Tube Voltage (kV)	61-85	54-84	60-90
Tube Current (mA)	4-10	1-16	4-12
Device Details			
Power Supply Voltage (V)	115	110-120	100-120
Dimensions (mm)	2230 x 1200 x 1200	2432 x 1000 x 1250	1832 x 1130 x 2383
Weight (kg)	150	113	160
2D/3D Exams			
3D Technology	Cone-beam computed tomography	Cone-beam computed tomography	Cone-beam computed tomography
FOV (D x H) (mm)	85 x 85	80 x 80	140 x 140 (max)
Exposure Time (sec)	13.8 (PAN) 18 (CT)	6 (PAN) 18 (CT)	17 (PAN) 15 (CT) 12 (CEPH)
Sensor Technology	CMOS Flat-panel detector	CMOS Flat-panel detector	CMOS Flat-panel detector
Sensor Pixel Pitch (µm)	100 x 100	127 x 127	75 x 75 (PAN/CEPH) 100 x 100 (CT)
Active Area (mm)	130 x 130	130 x 130	152 x 6.45 (PAN) 130.2 x 128 (CT) 228 x 6.45 (CEPH)

Safety and Effectiveness Information

The device labeling contains operating instructions for safe and effective use of X-VIEW, IMAGEN. Final device validation and risk assessment has been conducted to identify any potential hazards that could cause an error or injury based on its use. Appropriate steps have been taken to control all identified risks.

Safety, EMC and Performance Data Comparison to Predicate

The device has been tested for compliance to IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety and its derivatives. Specifically:

- IEC 60601-1: Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-3: Medical electric equipment Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-63: Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral x-ray equipment
- IEC 60601-1-2: Medical electrical equipment Part 1: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

- IEC 60601-1-6: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

IEC 62366: Medical devices – Application of usability engineering to medical devices

EN 62304: Medical device software – software life cycle processes

FDA Guidance “Guidance for the Submissions of 510(k)’s for Solid State X-Ray Imaging Devices” was performed for the detector of X-VIEW, IMAGEN. Detector test results are as follows:
The MTF of the X-VIEW, IMAGEN detector shows the resolution of 50-57% at 1.0 lp/mm and the DQE of them shows the performance of about 70% at 0 lp/mm. The dynamic range of them shows 66-69 dB.

X-VIEW, IMAGEN was tested for safety and effectiveness related in a Clinical Evaluation report in which volumetric reconstructive images of a human subject were acquired.

All test results were satisfactory. The result of bench and clinical evaluation indicates that the new device is as safe and effective as the predicate devices.

Conclusion

X-VIEW, IMAGEN performs the same functions in the same environment as the predicate device. It shares the same technology as the predicate device. It is based on wellknown technology. It is as safe and effective as the predicate devices. We believe it does not introduce any new potential safety risks and is substantially equivalent to the predicate devices.