



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

Panoramic Corp.  
% Daniel Kamm, P.E.  
Principal Consultant  
Kamm & Associates  
8870 Ravello Court  
NAPLES FL 34114

February 4, 2016

Re: K152489

Trade/Device Name: ENCOMPASS Eagle 3D CBCT/Panoramic/Cephalometric  
Dental X-ray

Regulation Number: 21 CFR 892.1750

Regulation Name: Computed tomography x-ray system

Regulatory Class: II

Product Code: OAS

Dated: January 18, 2016

Received: January 22, 2016

Dear Mr. Kamm:

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a large, prominent "R" and "O".

Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K152489

Device Name

ENCOMPASS Eagle 3D CBCT/Panoramic/Cephalometric Dental X-Ray

Indications for Use (Describe)

ENCOMPASS Eagle 3D is intended to acquire two-dimensional digital panoramic and cephalometric radiographies, and multi-field of view 3D computed tomography images of dento-maxillo-facial region for the purpose of advanced diagnosis at the direction of qualified dental healthcare 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) Summary K152489

*This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.*

Date prepared: January 18, 2016

1. Company and Correspondent making the submission:
  - Name – Panoramic Corp.
  - Address – 4321 Goshen Rd., Fort Wayne, IN 46818
  - Telephone – 800-654-2027
  - Contact – Doug Pack
  
2. Device:
  - Device trade name, ENCOMPASS Eagle 3D
  - Device common name, CBCT/Panoramic/Cephalometric Dental X-Ray
  - Regulation number, 21 CFR §892.1750
  - Regulation name, Computed tomography x-ray system
  - Classification: 2
  - Product code) OAS
  
3. Predicate Device: The Encompass 3D is substantially equivalent to the following legally marketed device: K122199, Prexion3d Eclipse made by The Yoshida Dental Mfg. Co., Ltd. 21 CFR§ 892.1750, Class 2 Product code OAS.
  
4. Description: The ENCOMPASS Eagle 3D is a complete 3-in-1 system for dental imaging capable of make Tomography, Digital Panoramic Profiles and Digital Cephalometric Profiles. The machine uses a CCD sensor technology with the traditional scintillator technologies and auto image processing that speeds up the diagnostic and improves the clinic workflow. The equipment has three movement axes (two in orthogonal directions and one rotational) making it possible to execute elaborate imaging profiles. It features a complex profile movement around the dental arch and radiographic emission compensation in the spinal region, when necessary reconstructing the dental arch into a plane image. Each individual profile prioritizes a set of characteristics improving diagnostic capabilities. For example, the standard panoramic prioritizes image layer width, constant vertical magnification and homogeneous exposure along the whole image. Likewise, the low dosage profile prioritizes the reduction of dosage (time and anodic current). *The Encompass Eagle 3D complies with applicable aspects of 21CFR 1020.30,31, and 33.*
  
5. Indications for use: ENCOMPASS Eagle 3D is intended to acquire two-dimensional digital panoramic and cephalometric radiographies, and multi-field of view 3D computed tomography images of dento-maxillo-facial region for the purpose of advanced diagnosis at the direction of qualified dental healthcare professionals.
  
6. Comparison with predicate devices: The PREXION 3D ECLIPSE consists of scanner intended to produce two-dimensional digital panoramic and cephalometric images, and three-dimensional digital X-ray images of the dento-maxillo-facial region at the direction of healthcare professionals as diagnostic support. The new device ENCOMPASS Eagle 3D is a digital capture type CBCT/Pan/Ceph system. Technologies employed by the predicates and our new device are nearly identical. A comparison table follows.

ITEM		ENCOMPASS Eagle 3D K152489	PREXION 3D ECLIPSE K122199
Indications for use		ENCOMPASS Eagle 3D is intended to acquire two-dimensional digital panoramic and cephalometric radiographies, and multi-field of view 3D computed tomography images of dento-maxillofacial region for the purpose of advanced diagnosis at the direction of qualified dental healthcare professionals.	PREXION 3D ECLIPSE is intended to produce two dimensional digital panoramic and cephalometric images, and three-dimensional digital X-ray images of dento-maxillofacial region at the direction of healthcare professionals as diagnostic support.
X Ray Generation Device	Tube Voltage	60-85 kV	50-90 kV
	Tube Current	4-8 mA	1-4 mA
	Focal Spot Size	0.5 mm	0.2 mm
X Ray image capturing device	Detector	CMOS (CT) CCD (Panoramic) CCD (Ceph)	FPD
	Pixel Size	100 µm (CT) 108 µm (Panoramic) 108 µm (Ceph)	200 µm (CT) 100 µm (Panoramic) 54 µm (Ceph)
	Pixel Number	1316 x 1312 (CT) 64 x 1395 (Panoramic) 64 x 2040 (Ceph)	640 x 656 (CT) 80 x 1312 (Panoramic) 128 x 4080 (Ceph)
	Size of Area receiving X-Ray	131.6 x 131.2 mm (CT) 6.9 x 151 mm (Panoramic) 6.9 x 221 mm (Ceph)	128.1 x 131.3 mm (CT) 8 x 131.3 mm (Panoramic) 6.9 x 312 mm (Ceph)
	Number of Bit	14 bits (CT,) 16 bits (Ceph, Panoramic)	14 bits (CT, Panoramic) 16 bits (Ceph)
Scanner	SID/SOD	634mm/400mm(CT) 564mm/400mm (Panoramic) 1681mm/1511mm (Ceph)	620mm/400mm(CT, Panoramic) 1650 mm/1500 mm (Ceph)
	Dimension (WxDxH)	1511mm x 1074mm x 1742mm	1245mm x 1288mm x 2045mm (CT, Panoramic) 1805mm x 1288mm x 2045mm (Ceph)
	Weight	115kg (CT, Panoramic) 152kg (Ceph)	260kg (CT, Panoramic) 300kg (Ceph)
Imaging Mode		CT scan, Panoramic scan, Cephalometric radiography	CT scan, Panoramic scan, Cephalometric radiography
Panoramic Scan Performance		Standard Panoramic: 14 sec TMJ Panoramic: 14 sec Maxillary Sinus: 8 sec Improved Orthogonality Panoramic: 14 sec	Standard Mode : 14 sec

ITEM		ENCOMPASS Eagle 3D K152489	PREXION 3D ECLIPSE K122199
		Low Dose Panoramic: 11 sec Child Panoramic: 10.5 sec Bitewing: 7.6 sec Improved Bitewing: 7.6 sec	
Cephalometric Radiography		LA, PA, Carpus, Oblique: 6.6, 10, 11, 16.5 sec	LA, PA, Carpus: 8, 10, 12, 15 sec
CT Scan Performance	Scan Time	Low Dose: 16.5 sec Standard Dose: 20.5 sec High Definition: 25.5 sec Ultra High Definition: 32.0 sec	Light Mode: 8.7 sec High Definition Mode: 8.7 sec Ultra High Definition Mode: 17.4 sec Wide Mode: 9.1 sec x 2
	FOV (voxel size)	Low Dose, Standard Dose, High Definition, Ultra High Definition: φ50mm x H50 mm (0.08, 0.10, 0.13, 0.16 mm) φ80mm x H60 mm (0.13, 0.16, 0.20, 0.25 mm) φ80mm x H80 mm (0.13, 0.16, 0.20, 0.25 mm)	Light Mode, High Definition Mode, Ultra High Definition Mode: Diameter 81mm, H75mm
		Low Dose, Standard Dose, High Definition, Ultra High Definition: φ80mm x H120 mm (0.16, 0.20, 0.25, 0.32 mm) φ80mm x H160 mm (0.25, 0.32, 0.40, 0.50 mm)	Wide Mode: Diameter 113mm, H72mm
MTF: 70%		1.05 lp/mm	1.2 lp/mm
MTF: 40%		2.2 lp/mm	2.2 lp/mm
DQE@0 lp/mm		46.9%	51.7%
Photo			
Operating temperature		+15°C to +30°C	Not stated
Mains voltage supply		110/127/220 or 240 Vac (50/60 HZ)	230/240 Vac ±10% / 115 Vac (50/60 HZ)
Power consumption		1.4 kVA	Not Stated

ITEM	ENCOMPASS Eagle 3D K152489	PREXION 3D ECLIPSE K122199
Operation Mode	CBCT, Panoramic or Cephalometric	SAME
Generator type	High Frequency 100 kHz High	High Frequency 40 kHz

7. Safety, EMC, Biocompatibility (N/A) and Performance Data: Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2(2001). Compliance testing was performed for the applicable portions of the following X-Ray standards: IEC 60601-1-3/2001; IEC 60601-2-7/2001; 60601-2-28/2001; IEC 60601-2-32/2001. Performance testing: MTF and DQE measurements were taken and compared to the predicate. See table above. 3D performance testing was performed yielding the MTF curve and the NPS, noise power spectrum. Accuracy testing and software validation was performed. The Encompass Eagle 3D complies with applicable aspects of 21CFR 1020.30,31, and 33. All test results were satisfactory.
  
8. Clinical Data: In accordance with the FDA guidance document on Solid State X-Ray Imaging Devices, clinical images were acquired with both the new device and the predicate device. They were compared by a licensed dentist. The Images from the Encompass machine are comparable in diagnostic ability, sharpness and quality to images from the Predicate device.
  
9. Conclusion: In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Panoramic Corp. concludes that the ENCOMPASS Eagle 3D CBCT/Panoramic/Cephalometric X-Ray is safe and effective and substantially equivalent to predicate devices as described herein.