August 10, 2021

Alliage S/A Industrias Médico Odontológica
℅ Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

Re: K210820
Trade/Device Name: EAGLE EDGE AXR90 and AXR120
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: July 9, 2021
Received: July 12, 2021

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. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210820

Device Name
EAGLE EDGE AXR90 and AXR120

Indications for Use *(Describe)*
The EAGLE EDGE AXR90 and AXR120 are CBCT / Panoramic / Cephalometric X-Ray units designed to obtain 2D and 3D radiological images of the oral anatomy, including teeth, maxillofacial areas, oral structures, carpal images and head-neck bone regions. This system is exclusively for dental use and should be handled only by qualified health 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 K210820

Alliage S/A Indústrias Médico Odontológica.
Rodovia Abrão Assed, Km 53+450m
Recreio Anhanguera, CEP 14097-500,
Ribeirão Preto - São Paulo- Brazil
Tel +55 16 3512-1212

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92. Date prepared: August 6, 2021

1. **Company and Correspondent making the submission:**
   Name: Alliage S/A Indústrias Médico Odontológica
   Address: Rod. Abrão Assed, Km 53+450m Recreio Anhanguera, CEP 14097-500, BRAZIL.
   Telephone: +55 16 3512-1212
   Contact: Daniel Camargo

2. **Trade /Proprietary Name:** **EAGLE EDGE AXR90 and AXR120**
   Device: **X-Ray, Tomography, Computed, Dental**
   Regulation Description: **Computed tomography x-ray system.**
   Regulation Medical Specialty: **Radiology**
   Review Panel **Radiology**
   Product Code **OAS**
   Regulation Number **892.1750**
   Device Class **2**

3. **Legally Marketed Predicate Device Information:**
   510(k) Number: **K152489**
   Manufacturer: **Panoramic Corp**
   Trade /Proprietary Name **ENCOMPASS Eagle 3D CBCT**
   Device: **X-Ray, Tomography, Computed, Dental**
   Regulation Description: **Computed tomography x-ray system.**
   Regulation Medical Specialty: **Radiology**
   Review Panel **Radiology**
   Product Code **OAS**
   Regulation Number **892.1750**
   Device Class **2**

4. **Description:**
   EAGLE EDGE Models AXR90, AXR120 are complete 3-in-1 dental imaging systems capable of generating panoramic, cephalometric and tomographic images using cone beam computerized tomography (CBCT) technique. The AXR90 has a maximum kVp of 90 while the AXR120 has a maximum kVp of 120. The digital acquisition process utilizes one or more X-ray sensors and automatic image processing that allow you to increase the speed of diagnosis and improve the workflow of your clinic.
   Models: (Customer decides which modalities are desired)

Pan only
Pan + Ceph (Single Sensor)
Pan + Ceph (Two Sensors)
CBCT + PAN
CBCT + PAN + CEPH

Sensor Technology Discussion:
For Panoramic only configuration we have validated two possible detector models are:
The Alliage SPB PAN (CMOS 157.5x6.4) OR the XINEOS 1501 (CMOS 152x6.8) for panoramic acquisition

For Panoramic with Cephalostat configuration it has two options it depends on the client choice if he wants one single mobile digital sensor or two fixed digital sensor.
For option with one single mobile digital sensor two possible detector models are:
Alliage SPB CEPH (CMOS 220x6.4) OR XINEOS 2301 (CMOS 225.2x6.8) for panoramic and cephalometric acquisitions

For the option with two fixed digital sensor possible detector models are:
Alliage SPB PAN (CMOS 157.5x6.4) OR the XINEOS 1501 (CMOS 152x6.8) for panoramic acquisition
Alliage SPB CEPH (CMOS 220x6.4) OR XINEOS 2301 (CMOS 225.2x6.8) for cephalometric acquisition

For Tomography configuration, the detector model is VIVIX 0606C (CMOS 153.2x153.2) for CBCT and Panoramic acquisition

For Tomography with cephalostat configuration possible detector models are:
VIVIX 0606C (CMOS 153.2x153.2) for CBCT and Panoramic acquisition
Alliage SPB CEPH (CMOS 220x6.4) OR XINEOS 2301 (CMOS 225.2x6.8) for cephalometric acquisition

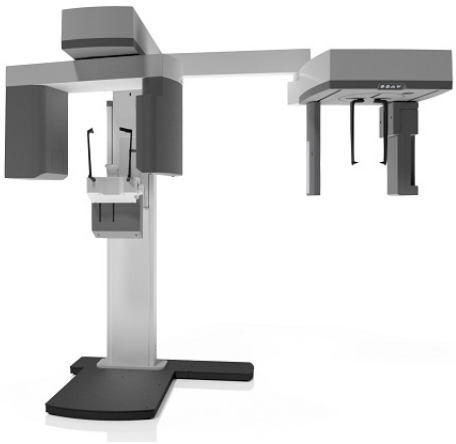
5. Indications for use:

The EAGLE EDGE AXR90 and AXR120 are CBCT / Panoramic / Cephalometric X-Ray units designed to obtain 2D and 3D radiological images of the oral anatomy, including teeth, maxillofacial areas, oral structures, carpal images and head-neck bone regions. This system is exclusively for dental use and should be handled only by qualified health professionals.

6. Comparison with predicate devices:

The Encompass Eagle 3D CBCT/panoramic/cephalometric Dental X-ray consists of a configuration which implements 3D use a Cone beam Computed Tomography. 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. The new device EAGLE EDGE AXR90 and AXR120 CBCT / Panoramic / Cephalometric X-Ray is digital capture type CBCT / Panoramic / Cephalometric system. The technologies employed by the predicate and our new device are almost identical.

ITEM		ENCOMPASS 3D K152489	EAGLE EDGE AXR90, AXR120
Indications for use		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.	The EAGLE EDGE AXR90 and AXR120 are CBCT / Panoramic / Cephalometric X-Ray units designed to obtain 2D and 3D radiological images of the oral anatomy, including teeth, maxillofacial areas, oral structures, carpal images and head-neck bone regions. This system is exclusively for dental use and should be handled only by qualified health professionals. (SAME, different wording)
X-Ray Generation Device	Tube voltage	60-85 kV	AXR90: 60- 90kV (at 90kV max. 12.5mA) AXR120: 60-120 kV (at 120kV max. 8mA) (Higher kV can provide better images)
	Tube Current	4-8 mA	3.2-16 mA
	Focal spot Size	0.5 mm	0.5 mm
X-Ray image capturing device	Detector	CMOS (CT) CCD (Panoramic) CCD (Ceph)	CMOS/a-Si (CT) CMOS (Panoramic) CMOS (Ceph)
	Pixel Size	100 µm (CT) 108 µm (Panoramic) 108 µm (Ceph)	119 µm (CT) 100 µm (Panoramic) 100 µm (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)	214.9 x 215,5 (CT) 6.8 x 225,2 (Panoramic) 6.8 x 228 (Ceph) Larger panel size for CT. Otherwise not an important difference.
	Number of Bits	14 bits (CT) 16 bits (Ceph, Panoramic)	16 bits (CT) 14 bits (Panoramic, Ceph) Not a useful difference
Scanner	SID/SOD	634mm/400mm(CT) 564mm/400mm (Panoramic) 1681mm/1511mm (Ceph)	620mm/400mm (CT) 620mm/400mm (Panoramic) 1732,5mm/1473,65mm (Ceph)
	Dimension (WxDxH)	1511mm x 1074mm x 1742mm	Main Unit: 1711 X 586 X 1318 Cephalostat: 1105 X 665 X 963mm Base: 1215 X 770 X 300mm Comparable dimensions

ITEM		ENCOMPASS 3D K152489	EAGLE EDGE AXR90, AXR120
	Weight	152 Kg	160 Kg Comparable weight
Imaging Mode		CT scan, Panoramic scan, Cephalometric radiography	CT scan, Panoramic scan, Cephalometric radiography SAME
Panoramic Scan Performance		Standard Panoramic: 14 sec TMJ Panoramic: 14 sec Maxillary Sinus: 8 sec Improved Orthogonality Panoramic: 14 sec Low Dose Panoramic: 11 sec Child Panoramic: 10.5 sec Bitewing: 7.6 sec Improved Bitewing: 7.6 sec	Standard Panoramic: 14 sec Fast Panoramic: 10 sec Improved orthogonality: 14 sec Infant: 10 sec Maxillary sinus: 8 sec TMJ: 10 sec TMJ PA: 10 sec Bitewing: 7.6 sec Lateral section: 6 sec Center section: 3.5 sec
Cephalometric Radiography		LA, PA, Carpus, Oblique: 6.6, 10, 11, 16.5 sec	AP/PA, LL, Carpal, Oblique: 4~16,5 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	Fast Scout: 0.1 sec Full Scout: 0.2 sec Low Dose: 10 sec Standard: 15 sec High Definition: 20 sec Ultra High definition 25 sec
	FOV (Voxel Size)	5x5mm; 6x8mm; 8x8mm; 8x12mm 8x16mm	5x5mm; 6x9mm; 9x9mm; 9x16mm 15x16mm; 21x16mm
Photo			

7. **Non-clinical Testing Performed: Safety, EMC, Biocompatibility and Performance Data:**
   Safety and performance testing was conducted by an internationally recognized testing laboratory Underwriters Laboratories standard(s) for Safety:
   ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012), IEC 60601-1 Edition 3.1 (2012)
   Additional Standards applied:

IEC 60601-1-3:2008 (Second Edition) + A1:2013, IEC 60601-1-6:2010 (Third Edition) + A1:2013, IEC 60601-2-63:2012 (First Edition)
A different accredited laboratory "IBEC" (Instituto Brasileiro de Ensaios de Conformidade Ltda) tested the system according to IEC 60601-1-2 Ed. 4.0 (2014) –Collateral standard: Electromagnetic disturbance – Requirements and tests. All standards tests passed.
Biocompatibility evaluation was performed in accordance with EN ISO 10993-1: 2009 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. These tests were conducted for irritation, sensitization, and cytotoxicity. All tests passed.
Risk analysis and software validation was performed according to the FDA guidance document *Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (for a moderate level of concern.)
Consideration was given to cybersecurity via compliance with the recommendations of the FDA Guidance: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff.*
Each unit manufactured is 100% tested for Connection to the Software, Exposure Accuracy, Tube Voltage and Exposure Time, Reproducibility, Beam Quality, Tube Efficiency, and Leakage Radiation.
Image evaluation was performed by both licensed dentist and a USA Board Certified Radiologist.. Dental images were compared to the images obtained on the predicate device and found to be equivalent or better. In addition, the Radiologist evaluated the effectiveness of the motion artifact reduction software and the metal artifact reduction software. These software features were found to be effective.

8. **Clinical Testing Performed:** Sample X-Ray images were taken by the Eagle Edge AXR90 and AXR120 across the different operational modes, i.e. Panoramic, Cephalometric, tomographic/CBCT scans. These images were evaluated by an American Board of Radiology certified radiologist.

9. **Conclusions:**
According to the Federal Food, Drug and Cosmetic Law, 21 CFR Part 807 and based on the information provided in this pre-marketing notification, Alliage S/A Indústrias Médico Odontológica concludes that EAGLE EDGE AXR90 and AXR120 CBCT / Panoramic / Cephalometric X-Ray is safe and effective and substantially equivalent to predicate devices, as described in this document.