April 7, 2023

Alliage S/A Industrias Medico Odontológica.
% Daniel Kamm
Principal Engineer
Kamm & Assosciates
8870 Ravello Ct
Naples, FL 34114

Re: K223816
Trade/Device Name: Dental CT Scanner AXR
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: December 20, 2022
Received: December 20, 2022

Dear Daniel 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,

Digitally signed by Gabriela M. Rodal -S for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of 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)*
K223816

Device Name
DENTAL CT SCANNER AXR

Indications for Use *(Describe)*
The DENTAL CT SCANNER AXR is 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.**

**510(k) Summary K223816**

**Alliage S/A Industrias Medico 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: April 7, 2023

1. **Company and Correspondent making the submission:**
   **Name: Alliage S/A Industrias Medico 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:** | **DENTAL CT SCANNER AXR** |
   | **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:** | **K210820** |
   | **Manufacturer:** | **Alliage S/A Industrias Medico Odontológica** |
   | **Trade /Proprietary Name** | **EAGLE EDGE AXR90, 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** |

4. **Description:** The Dental CT Scanner AXR is a complete 4-in-1 dental imaging system capable of generating panoramic, cephalometric and tomographic images using cone beam computerized tomography technique (Cone Beam).
   The AXR90 has a maximum kVp of 90 while the AXR120 has a maximum kVp of 120. The digital acquisition process utilizes an X-ray sensor 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)
CBT + 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.

“Mult Slice” is a new software functionality that allows the user to adjust the position of the flattened arch image on the image cutting plane. To better explain, for dental panoramic image, the cutting plane is a region in which the structures positioned in it are reasonably well defined in the final image. In a conventional software, the equipment generate only one Slice of the panoramic image in the most favorable theoretical position in the cutting plane. In that case, image definition will depend on the patient being physically positioned on the equipment as close as possible to this ideal position. With the Mult Slice function, the software generates multiple images varying the ideal theoretical position. Thus, even if the patient is poorly positioned, it is possible to find the position where the image is best defined for the exam. Thus, by virtually moving the patient's ideal position, we can seek the best-defined image in the final image for each exam**.”**

5. **Indications for use:** The DENTAL CT SCANNER AXR is 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 DENTAL CT SCANNER AXR 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 DENTAL CT SCANNER AXR is a digital capture type CBCT / Panoramic / Cephalometric system. The technologies employed by the predicate and our new device are almost identical.

Comparison Table

| **ITEM** | | **EAGLE EDGE AXR90 and AXR120 X-Ray, Tomography, Computed, Dental K210820** | **EAGLE EDGE and DABI ATLANTE / AXR120 and AXR90 Dental CT Scanner AXR** |
|---|---|---|---|
| Indications for use | | EAGLE EDGE / DABI ATLANTE is designed to obtain radiological images of the oral anatomy, including teeth, maxillofacial areas, oral structures, carpal images and head-neck bone regions, and the same system, of exclusive dental use should be handled by health professionals with qualification and duly qualified. | The DENTAL CT SCANNER AXR is 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.<br>(SAME) |
| X-Ray Generation Device | Tube voltage | 60-120 kV | 60-120 kV (SAME) |
| | Tube Current | 3.2-16 mA | 1.8-16 mA (Greater range) |
| | Focal spot Size | 0.5 mm | 0.2/0.5 mm (Smaller focal spot allows for detail enhancement) |
| X-Ray image capturing device | Detector | CMOS/a-Si (CT)<br>CMOS (Panoramic)<br>CMOS (Ceph) | CMOS/a-Si (CT)<br>CMOS (Panoramic)<br>CMOS (Ceph)<br>(SAME) |
| | Pixel Size | 151 µm (CT)<br>100 µm (Panoramic)<br>100 µm (Ceph) | 151 µm (CT)<br>100 µm (Panoramic)<br>100 µm (Ceph)<br>(SAME) |
| | Size of Area receiving X-Ray | 214.9 x 215.5 (CT)<br>6.8 x 225.2 (Panoramic)<br>6.8 x 228 (Ceph) | 214.9 x 215.5 (CT)<br>6.8 x 225.2 (Panoramic)<br>6.8 x 228 (Ceph)<br>(SAME) |
| | Number of Bit | 16 bits (CT)<br>14 bits (Panoramic, Ceph) | 16 bits (CT)<br>14 bits (Panoramic, Ceph)<br>(SAME) |
| Scanner | SID/SOD | 620mm/400mm (CT)<br>620mm/400mm (Panoramic)<br>1732.5mm/1473.65mm (Ceph) | 620mm/400mm (CT)<br>620mm/400mm (Panoramic)<br>1732.5mm/1473.65mm (Ceph)<br>(SAME) |
| | Dimension (WxDxH) | 1607mm x 1007mm x 1504mm | 1607mm x 1007mm x 1504mm<br>(SAME) |

| ITEM | | EAGLE EDGE AXR90 and AXR120 X-Ray, Tomography, Computed, Dental K210820 | EAGLE EDGE and DABI ATLANTE / AXR120 and AXR90 Dental CT Scanner AXR |
|---|---|---|---|
| | Weight | 160 Kg | 160 kg (SAME) |
| Imaging Mode | | CT scan, Panoramic scan, Cephalometric radiography | CT scan, CT scan 0.2FS, Panoramic scan, **Mult slice panoramic scan**, Cephalometric radiography (Mult slice added) (**Different**) |
| Panoramic Scan Performance | | Standard Panoramic: 14 s<br>Fast Panoramic: 10 s<br>Improved orthogonality: 14 s<br>Infant: 10 s<br>Maxillary sinus: 8 s<br>TMJ: 10 s<br>TMJ PA: 10 s<br>Bitewing: 7.6 s<br>Lateral section: 6 s<br>Center section: 3.5 s | Standard Panoramic: 14 s<br>Fast Panoramic: 10 s<br>Improved orthogonality: 14s<br>Infant: 10s<br>Maxillary sinus: 8s<br>TMJ: 10s<br>TMJ PA: 10s<br>Bitewing: 7.6s<br>Lateral section (left or right): 6s<br>Center section: 3.5s<br>(SAME) |
| Cephalometric Radiography | | AP/PA, LL, Carpal, Oblique: 4.1-16,5 sec | AP/PA, LL, Carpal, Oblique: 4.1-16.5 sec , **Fast Ceph Mode from 2.5 to 10s (Different)** |
| CT Scan Performance | Scan Time | Fast Scout: 0.1 sec<br>Full Scout: 0.2 sec<br>Low Dose: 10 sec<br>Standard: 15 sec<br>High Definition: 20 sec<br>Ultra High definition 25 sec | Fast Scout: 0.1 sec<br>Full Scout: 0.2 sec<br>Low Dose: 10 sec<br>Standard: 15 sec<br>High Definition: 20 sec<br>Ultra High definition 25 sec<br>(SAME) |
| | FOV (Voxel Size) | 5x5mm; 6x9mm; 9x9mm; 9x16mm; 15x16mm; 21x16mm | 5x5mm; 6x9mm; 9x9mm; 9x16mm; 15x16mm; 21x16mm<br>(SAME) |
| 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*. We also took into consideration the FDA Guidance Document: *Pediatric Information for X-ray Imaging Device Premarket Notifications* when creating our labeling.

   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.

   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.

8. **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 Industrias Medico Odontológica concludes that DENTAL CT SCANNER AXR is safe and effective and substantially equivalent to predicated devices, as described in this document.**