January 3, 2024

Alliage S/A Industrias Médico Odontológica
℅ Daniel Kamm
Principal Engineer
Kamm & Assosciates
8870 Ravello Ct
NAPLES, FL 34114

Re: K233395
Trade/Device Name: Portable Dental X-Ray (AXR60 S); Portable Dental X-Ray (AXR65 S)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: EHD
Dated: October 2, 2023
Received: October 3, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic 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)*
K233395

Device Name
Portable Dental X-Ray (AXR60 S);
Portable Dental X-Ray (AXR65 S).

Indications for Use *(Describe)*
The Handheld X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.

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 K233395

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 872.1800.

Date prepared: December 15, 2023

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

2. **Trade /Proprietary Names:**
   Portable Dental X-Ray (AXR60 S);
   Portable Dental X-Ray (AXR65 S).
   Common Name: Portable X-ray System
   Regulation Name: Extra-oral Source X-ray System
   Regulation Number: 21 CFR 872.1800
   Primary Product Code: EHD
   Classification Name: Unit, X-ray, Extraoral with Timer
   Regulatory Class: II
   510k Review Panel: Dental

3. **Legally Marketed Predicate Device Information: K173319**
   Trade/Device Name: KaVo NOMAD Pro 2 Handheld X-ray System
   Common Name: Portable X-ray System
   Regulation Name: Extra-oral Source X-ray System
   Regulation Number: 21 CFR 872.1800
   Primary Product Code: EHD
   Classification Name: Unit, X-ray, Extraoral with Timer
   Regulatory Class: II
   510k Review Panel: Dental

4. **Description: These are hand-held portable battery operated x-ray generators for dental purposes. The Portable Dental X-Ray is an X radiation controlled emissions generator system, i.e., once put into service, is intended to be moved from one location to another by a person, used together with appropriate capture devices to generate intraoral radiological images for dental assessment, diagnosis and treatment. This equipment has exposure programs that can be applied to a variety of patients and has predefined exposure parameters depending on the type of patient. The operator is free to change these parameters depending on the situation. The equipment's human-machine interface consists of a control panel located on the top of the equipment, a local trigger button and a**

remote trigger (hard wired). The triggers are "dead-man" triggers, meaning they release and interrupt the exposure. The Portable Dental X-Ray was designed to be used in adult and children patients by trained dentists and dental technicians to produce X-ray images for diagnosis. The Portable Dental X-Ray is indicated for the production of intraoral medical images of teeth, mandible and oral structures; it assists in the diagnosis of diseases, planning of surgical treatment and monitoring. It is exclusively for dental use, and must be used and handled by qualified and trained health professionals according to the User Manual.

<u>Principles of operation</u>: The Portable Dental X-Ray is an autonomous X-ray emitting system, used to produce radiographic images. The X-ray beam passes through the patient's body, where a part of the X-rays is absorbed or spread by internal structures, and the rest of the X-rays are transmitted to a detector (e.g., a film, digital sensor or phosphorous plate) for recording or further processing by a computer. The generator can be used with any of the three detector technologies that require technique factors within the range of capabilities of these models.

<u>Image receptor compatibility</u>: These devices will work with film, image receptor plates, and digital image receptors within the technique capability of the generator, which is 60 or 65 kVp and 2.5 mA with up to a 1 second exposure time. For example, a typical digital image receptor can work effectively at 60 kVp, 2.5 mA, 0.2 seconds, well within the capability of these generators.

5. **Indications for use:**
   The Handheld X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.

6. **Comparison with predicate device:**
   A comparison table follows:

PRODUCT	**K173319 KaVo NOMAD Pro 2 Handheld X-ray System**	**Portable Dental X-Ray (AXR60 S); Portable Dental X-Ray (AXR65 S).**
Indications for use	The KaVo NOMAD Pro 2 Handheld X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.	The Handheld X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors. SAME
Models	Only one, 60 kV (DC) 2.5 mA	Two, one with 60 kV 2.5 mA and one with 65 kV 2.5 mA ALMOST IDENTICAL
Timer Range	0.02–1.00 sec. (in 0.01 second steps.)	0.01 to 1 second (With 0.01 second steps) Sligthly greater range of steps.
Duty Cycle	1:60	1:60 SAME
Waveform	DC	DC SAME
mA	2.5 mA fixed	2.5 mA fixed SAME
Where Used	Dental offices	SAME
Operating Temp. Range	–5°C to +40°C	+10°C to +35°C (Dental office environment)

PRODUCT	K173319 KaVo NOMAD Pro 2 Handheld X-ray System	Portable Dental X-Ray (AXR60 S); Portable Dental X-Ray (AXR65 S).
Supply Voltage (For battery charging)	AC Line 110/120V or 220/240V	AC Line: 100-240 V~, 50-60 Hz SAME (Charger is UL listed)
Battery	Rechargeable Lithium-ion, 22.2V; 1.7 A-hr	Rechargeable Lithium-ion, 21,6V – 2.50Ah
Electrical Safety Standards	AAMI ES60601-1:2005/(R)2012 And A1:2012	ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 SAME
EMC	IEC60601-1-2 Ed. 4	IEC60601-1-2 Ed. 4 SAME
X-Ray Performance	21 CFR 1020.30, 1020.31; IEC60601-1-3; IEC60601-2-65	21 CFR 1020.30, 1020.31; IEC 60601-1-3:2008 (Second Edition) + A1:2013, IEC 60601-1-6:2010 (Third Edition) + A1:2013, IEC 60601-2-65:2012 (First Edition) SAME
Photos	**KaVo NOMAD Pro 2** 	**AXR60 S, AXR65 S** 

7. **Non-clinical Testing Performed:** Safety, EMC, and Performance Data:

Electrical Safety: The device has a certificate of compliance issued by UL, Report Reference E503536-D1002-0/A0/C0-UL, 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. Additional Standards: IEC 60601-1-3:2008 (Second Edition) + A1:2013, IEC 60601-1-6:2010 (Third Edition) + A1:2013, IEC 60601-2-65:2012 (First Edition). The AC Power supply used for charging the battery is a medical grade UL listed, file UL62368-1. The battery pack consists of six cells connected in series connected to an integrated safety protection circuit board.

Electromagnetic Compatibility (EMC): IEC 60601-1-2 Ed. 4.0 (2014) – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard:

Electromagnetic disturbance – Requirements and tests. The device was evaluated according to IEC TR 60601-4-2, Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

FDA Guidance Document Utilized: Radiation Safety Considerations for X-ray Equipment Designed for Hand-Held Use. The scattered radiation from the device (in operation) was characterized in the entire volume surrounding the device and was found to be zero nGy in the volume space that would be occupied by the operator hand holding the device.

Image Evaluation: Using a digital image receptor (cleared in K230732) images were acquired and were found to be of diagnostic quality for dental applications.

Software (Firmware) Validation: Documentation was provided in compliance with FDA Guidance Document: Content of Premarket Submissions for Device Software Functions (for a Basic Documentation Level.) Risk analysis documentation was provided.

Bench Testing was performed to confirm compliance with the FDA Radiation Safety requirements of the Code of Federal Regulations including: accuracy and reproducibility specifications. (kV, ma, time) and aluminum equivalence.

8. **Clinical Testing Performed:** Clinical testing is not required for a finding of substantial equivalence.

9. **Conclusions:** Based on a comparison of intended use, indications, technological characteristics, principle of operation, features and performance data, the Portable Dental X-Ray (AXR60 S); and Portable Dental X-Ray (AXR65 S) devices are deemed to be substantially equivalent to the predicate device.