April 11, 2023

Alliage S/A Industrias Medica Odontológico
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

Re: K230732
Trade/Device Name: Eagle S/Saevo Slim/D700 Slim
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH, EHD, MQB
Dated: March 16, 2023
Received: March 16, 2023

Dear Prithul Bom:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological 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)*
K230732

Device Name
EAGLE S/SAEVO SLIM/D700 SLIM

Indications for Use *(Describe)*
The Intraoral Dental Digital Imaging Sensor is aimed at the acquisition of intra-oral medical images from teeth, jaw and oral structure, only for exclusive dental use and must be handled by trained and 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary K230732

EAGLE S/SAEVO SLIM/D700 SLIM Intraoral Dental Digital Imaging Sensor

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 872.1800. Date prepared: March 23, 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: EAGLE S/SAEVO SLIM/D700 SLIM**
   Device: Dental, Intraoral, Sensor
   Regulation Description: Extraoral Source X-ray system
   Regulation Medical Specialty: Dental
   Review Panel: Radiology
   Classification Product Code: MUH **Secondary Product Codes:** EHD, MQB
   Regulation Number: 872.1800
   Device Class: 2

3. **Legally Marketed Predicate Device Information:**
   510(k) Number: K162585
   Manufacturer: Suni Medical Imaging, Inc
   Trade /Proprietary Name: SuniIQ Digital Radiography System
   Device: Dental, Intraoral, Sensor
   Regulation Medical Specialty: Dental
   Review Panel: Radiology
   Classification Product Code: MUH
   Regulation Number: 872.1800
   Device Class: 2

4. **Description:**
   This Intraoral Dental Digital Imaging Sensor employs CMOS (Complementary Metal-Oxide-Semiconductor), protective optical fiber and scintillator. There are three names proposed for this device: EAGLE S/ SAEVO SLIM/D700 SLIM. The three models are all identical except for the name. This sensor was developed to obtain a high-quality x-ray image from the human arch and its structures. The acquisition process is made by positioning the sensor inside the mouth, behind the structure you want to perform the exam. The structure must be exposed to an x-ray dose using an external source. Once exposed, the sensor performs a conversion of the x-ray photons into a digital sign and transfers it to a computer through USB connection (Universal Serial Bus). The device performs the acquisition by positioning the sensor inside of the patient´s mouth, behind the structure to be examined. The structure should be exposed to a dose of x-rays, using an external source. Once exposed, the sensor performs a conversion of the x-ray photons into a digital signal and then transfers it to a computer via a Universal Serial Bus (USB) connection. The x-ray generator (an integral part of a complete dental x-ray system) is not part of the device. Device sensor sizes:

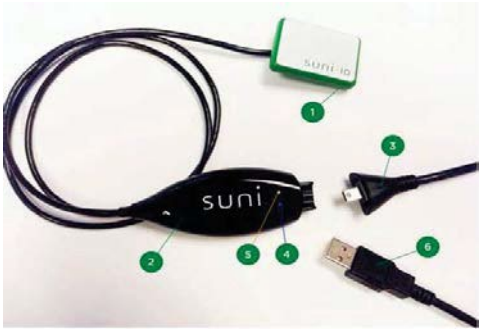
Size 1: 20 x 30 mm,
Size 2: 26 x 36 mm.
A description of the parts that accompany the product is below:

PARTS THAT ACCOMPANY THE PRODUCT

01 - Sensor
02 - Holder
03 - Installation flash drive (Software, Drivers, and Manuals)
04 - Silicone Front Cover: Protects sensor from biting

5. **Indications for use:**
The Intraoral dental digital imaging sensor is aimed at the acquisition of intra-oral medical images from teeth, jaw and oral structure, only for exclusive dental use and must be handled by trained and qualified health professionals.

6. **Comparison with predicate device:**
The predicate SuniIQ Digital Radiography System is a device intended for intra-oral x-ray examinations. Two sensor sizes are available. The new device Intraoral Dental Digital Imaging Sensor and its predicates are small digital imaging receptors that may be used in place of dental x-ray film.
Predicate sensor sizes: Size 1: 20.2 x 31.1 mm, Size 2: 26.2 x 35.2 mm.
Subject device sensor sizes: Size 1: 20 x 30 mm, Size 2: 26 x 36 mm.
The images are displayed on a computer workstation. The technologies employed by the predicate and our new device are almost identical. The proposed sensors have greater resolution than the predicate via smaller pixel size and greater numbers of total pixels. The same sensor sizes are available, and the computer interface is the same (USB). Both sensors use CMOS technology. Similarities: Indications for Use, available sizes, USB interface, CMOS technology employed. Differences: New device has greater resolution via smaller pixel size and greater number of pixels. The sensor sizes are nearly identical.
A comparison table follows:

PRODUCT	K162585 SuniIQ Digital Radiography System	EAGLE S/SAEVO SLIM/D700 SLIM Comparison + Discussion
Indications for use	The SuniIQ Digital Radiography system is used to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed and manipulated for diagnostic use by dentists.	The Intraoral dental digital imaging sensor is aimed at the acquisition of intra-oral medical images from teeth, jaw and oral structure, only for exclusive dental use and must be handled by trained and qualified health professionals. (Means the same thing)
Where Used	Clinics, hospitals, dental offices	SAME
Operating Temperature Range	Not stated	50˚F (10˚C) to 86˚F (30˚C)
Supply Voltage	+5 Vdc	+5 Vdc
Technology	CMOS	CMOS
Contrast	12 bits	12 bits SAME
Gray Level	4096	4096 SAME
Pixel Size	33 µm	20 µm
Number of pixels	600 x 900 Size 1 800 x 1000 Size 2	1000 x 1500 Size 1 1300 x 1800 Size 2
Line pairs/mm	15	25
MTF	Not speciified	MTF @ RQA5: >70% @ 1.47 lp/mm
DQE	Not specified	DQE @ RQA5: >61.3% @ 0 lp/mm
Active Sensor Area	Size 1: 20.2 x 31.1 mm Size 2: 26.2 x 35.2 mm	Size 1: 20 x 30 mm Size 2: 26 x 36 mm Almost identical sizes
Connection type	USB 2 or 3	USB 2 or 3
Replaceable Cable	No	Yes
Cable Length	6 ft. or 15 ft.	10 ft.
Patient Protection	(Not stated)	Single Use Patient Protective Barrier, FDA ckeared
Photo		

7. **Non-clinical Testing Performed: Safety, EMC, Biocompatibility and Performance Data:**
Safety testing: Electrical, mechanical, environmental safety and performance testing according to standard ABNT NBR IEC 60601-1:2016 (IEC 60601-1:2005/AMD1:2012) was performed by a nationally certified test laboratory. Note there is no electrical contact with the patient. Required tests passed. EMC testing was done according to 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 .
Biocompatibility testing was conducted to ISO 10993-1:2020 - Biological assessment of medical devices - Part 1: Assessment and testing within a risk management process. Tests conducted: Cytotoxicity; Sensitization; Intracutaneous irritation or reactivity. These items (although there is no direct patient contact) were tested:

Product Part	Material
Plastic Cover	Polycarbonate
USB Cable	Polyurethane
Silicone Cover	Silicone

The main patient contact material is the FDA cleared barrier sheath (K160232, Disposable Barrier Sleeves and Covers), not supplied by us. Although direct contact is unlikely inside the oral cavity, the subject dental sensor Eagle S has been tested for biocompatibility and all test results indicate compliance with biocompatibility standards. Successful software validation and risk analysis was conducted. All test results were satisfactory. Cybersecurity concerns were addressed via labeling and internal software controls. Reference: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*. The subject detector Eagle S has been bench tested, and successful test results (resolution, MTF, DQE) indicate substantial equivalence to the predicate.

8. **Clinical Testing Performed:** Device clinical testing has been performed, and the submitted intra-oral radiographs are deemed of diagnostic quality. Adequate clinical images are additional proof of device effectiveness, and they enforce the bench testing results that are already supporting our claim of substantial equivalence.

   We compiled a Clinical Performance Report for the Intraoral Dental Digital Imaging Sensor. The purpose was to provide analysis results and records of the requirements arising during the empirical evaluation process of the Intraoral Dental Digital Imaging Sensor clinical performance. In this report, all information related to the tests or studies required for the survey and characterization of the clinical performance based on empirical data are in their entirety. We also had an image quality analysis performed by a USA Board Certified Radiologist who compared the predicate images to the proposed device images. He concluded that the images are of good quality, clinically acceptable, and better than the predicate images.

9. **Conclusions: Our conclusions drawn from the nonclinical tests (discussed above) are that we have demonstrated that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device identified according to 807.92(b)(3), 57 FR 18066, Apr. 28, 1992, as amended at 59 FR 64295, Dec. 14, 1994,According to the Federal Food, Drug and Cosmetic Law, 21 CFR Part 872. Based on the information provided in this pre-marketing notification, Alliage S/A Indústrias Médica Odontológico concludes that Intraoral Dental Digital Imaging Sensor is safe and effective and substantially equivalent to predicated devices, as described in this document.**