Aribex
% Ms. Erika Martin
Senior Regulatory Affairs Manager
11727 Fruehauf Drive
CHARLOTTE NC 28273

November 16, 2017

Re: K173319
Trade/Device Name: KaVo NOMAD Pro 2 Handheld X-ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: October 19, 2017
Received: October 20, 2017

Dear Ms. Martin:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173319

Device Name
KaVo NOMAD Pro 2 Handheld X-ray System

Indications for Use *(Describe)*
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.

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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KaVo NOMAD™ Pro 2 Handheld X-ray System

1. **Submitter Information:**

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Contact Person: Erika Martin
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Date Prepared: October 19, 2017

2. **Device Name:**

- Proprietary Name: KaVo NOMAD Pro 2 Handheld X-ray System
- Manufacturer Name: Aribex
- Common Name: Extraoral Source X-ray System
- Classification Name: Extraoral Source X-ray System
- CFR Number: 872.1800
- Device Class: II
- Product Code: EHD

3. **Predicate Device:**

- Proprietary Name: NOMAD Pro X-ray System - (K081664)
- Manufacturer Name: Aribex
- Common Name: Extraoral Source X-ray System
- Classification Name: Extraoral Source X-ray System
- CFR Number: 872.1800
- Device Class: II
- Product Code: EHD

Reference Device:

- Proprietary Name: NOMAD Dental X-ray System - (K051795)
- Manufacturer Name: Aribex
- Common Name: Extraoral Source X-ray System
- Classification Name: Extraoral Source X-ray System
- CFR Number: 872.1800
- Device Class: II
- Product Code: EHD

4. **Description of Device:**

KaVo NOMAD Pro 2 Handheld X-ray System is a battery-operated, portable dental X-ray source designed for handheld operation. It is designed to produce diagnostic quality X-rays images utilizing either film or digital imaging techniques. The KaVo NOMAD Pro 2 Handheld X-ray System is designed for use in a dental office. It can also be used in other similar environments (orthodontic office, general practitioner's office, hospital ward, etc.) where appropriate safeguards are implemented. The device uses a rechargeable battery to allow for the use of the KaVo NOMAD Pro 2 Handheld X-ray System where transportation or use of other x-ray devices might be prohibitive due to the other device's size and/or lack of mobility.

The KaVo NOMAD Pro 2 Handheld X-ray System is an X-ray device with a DC generator. The handheld device features a main unit (tube head), rechargeable battery (handset), charger, and charger AC/DC power supply. The power is supplied by a rechargeable Lithium Ion battery core pack built into a handset. This facilitates portability of the device. A beam-limiting cone is incorporated within the device. Internal and external shielding provide sufficient radiation protection to allow the clinician to remain in the operatory with the patient.

To make the system as simple as possible for the operator, KaVo NOMAD Pro 2 Handheld X-ray System uses a fixed tube voltage of 60kV and a fixed tube current of 2.5mA. The only operator-adjustable parameter is the exposure time. This adjustment can be quickly accomplished through the user-friendly control panel.

Control buttons, display, and a trigger provide the primary operator interface. Exposures settings can be selected and displayed. Voltage (60 kV) and current (2.5 mA) are fixed with the exposure time varying based on patient type, detector type, and anatomical feature. Exposures can be completed using the trigger. The device can be used with three detector types: film, digital imaging intraoral sensors, and phosphor plates.

Accessories supplied with the finished device include:

- Alignment bars* (Class I Exempt, EHA, 21 CFR 872.1820)

Optional parts available:

- Rectangular collimator – rectangular and smaller exposure area
- Portable stand – for stationary positioning and use
- Tabletop stand – tabletop storage
- Wall hook – storage and display
- Hard shell carrying case – protection during transportation and storage

*Alignment bars are a device for positioning image receptors and are provided as a convenience and are not required to be used with the device.

Principle of Operation / Mechanism of Action:

The KaVo NOMAD Pro 2 Handheld X-ray System is used like any other extraoral dental X-ray source for intraoral application. An image receptor, such as film, is placed in the patient's oral cavity behind the teeth. The device is powered on, and the appropriate exposure time is set by the operator. The operator should follow appropriate instructions to ensure proper alignment of the X-ray beam to the receptor, and proper positioning of the receptor in the patient's mouth. To prevent inadvertent exposure to X-rays, the operator must first press and release the trigger to enable and then ready the device. A flashing green ENABLED indicator light and an audible signal confirm that the KaVo NOMAD Pro 2 Handheld X-ray System is enabled. X-rays are initiated by pulling and holding the trigger on the handle for the duration of the exposure. The system has numerous alarms and alerts to

communicate with the operator. These are described in the accompanying KaVo NOMAD Pro 2 Handheld X-ray System Operator Manual Section 6.

5. **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.

6. **Description of Substantial Equivalence:**
Technological Characteristics:

The KaVo NOMAD Pro 2 Handheld X-ray System retains the same basic design components and operating features as the predicate device, NOMAD Pro X-ray System (K081664).

The handheld device features a main unit (tube head), rechargeable battery (handset) and charger. The main components of the tube head including X-ray tube (60 kV, 2.5 mA), internal shielding and external backscatter shielding are unmodified from the predicate device. The functionality of the user interface is also unmodified from the previous product, including the pre-programmed exposure times for adult and pediatric patients.

The power is supplied by a rechargeable Lithium Ion battery core pack built into a handset. The design for the KaVo NOMAD Pro 2 Handheld X-ray System has been updated to a 21.6 VDC, 1.7 Ahr battery core pack compared to the predicate device (NOMAD Pro X-ray System – K081664) design of 22.2 VDC, 1.1 Ahr. The KaVo NOMAD Pro 2 Handheld X-ray System battery core pack is compliant with IEC 62133.

Testing has been completed on basic safety and essential performance and the device complies with AAMI ES60601-1; IEC 60601-1-2 (Ed. 4); IEC 60601-1-3, and IEC 60601-2-65. The Operator Manual, included in Section XIII Labeling, provides for updated information related to these international standards.

	NOMAD Pro X-ray System (Predicate Device)	**KaVo NOMAD Pro2 Handheld X-ray System**
INDICATIONS FOR USE:	The NOMAD Pro 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 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.
MECHANICAL:		
Size: Body	11"L x 10"H x 5.5"W	11"L x 10.5"H x 5.5"W
Weight	5.5 lbs.	6.0 lbs.
Source to skin distance	21 cm	
Cone diameter	6 cm	

User Interface	Same, plus several user-selectable preset times.	
Backscatter radiation protection	6.75" dia. Pb-filled acrylic plastic scatter shield	
Exposure switch	Trigger located on handset	
Tubehead mounting	Handheld	
ELECTRICAL:		
Control Mechanism (tube head):	Programmable logic device – Cyprus PSOC CY8C29866	
Energy Source	Rechargeable 22.2 V DC Li-polymer battery core pack	Rechargeable 21.6 V DC Li-ion battery core pack
Capacity	1.25 A-hr	1.7 A-hr
Casing	Soft Pack	Hard shell case
Connection method	Wiring harness within handset enclosure	Connector within handset enclosure
Recharge capability	60% remaining capacity after 400 cycles	70% remaining capacity after 300 cycles
Exposure Time	0.02 – 1.0 seconds in 0.01 increments	
Timer Accuracy	same	
mA	2.5 mA fixed	
kVp	60 kVp fixed	
Waveform	Constant Potential (DC)	
Duty Cycle	1:60	
EMI Coating	Nickel	Copper
Electrical Safety Standards	IEC60601-1, UL60601-1, EN60601-1	AAMI ES60601-1:2005/(R)2012 And A1:2012
EMI Standards	IEC60601-1-2 Ed. 2	IEC60601-1-2 Ed. 4
X-RAY PERFORMANCE:		
Performance Standard	21 CFR 1020.30, 1020.31; IEC60601-1-3; IEC60601-2-7	21 CFR 1020.30, 1020.31; IEC60601-1-3; IEC60601-2-65

Hence, the proposed device, KaVo NOMAD Pro 2 Handheld X-ray System is substantially equivalent to the predicate device, NOMAD Pro X-ray System.

Non-Clinical Test Data:

Testing was performed in accordance with the following international standards:

IEC 62304 Edition 1.1 2015-6 Medical Device Software – Software Life Cycle Processes

AAMI ANSI IEC 62304:2006 Medical Device Software – Software Life Cycle Processes

AAMI ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment – Part 1; General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)

IEC 60601-1-3 Edition 2.1 2013-04 Medical Electrical Equipment – Part 1-3: General Requirements for Basic Safety And Essential Performance – Collateral Standard: Radiation Protection in Diagnostic X-ray Equipment

IEC 60601-1-6 Edition 3.1 2013-10 Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety And Essential Performance – Collateral Standard: Usability

IEC 60601-2-65 Edition 1.0 2012-09 Medical Electrical Equipment – Part 2-65: Particular Requirements for the Basic Safety And Essential Performance of Dental Intra-Oral X-Ray Equipment

IEC 62366 Edition 1.1 2014-01 Consolidated Version Medical Devices – Application of Usability Engineering To Medical Devices

IEC 60601-1-2 Edition 4.0 2014-02 Medical Electrical Equipment – Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements And Tests

ISO 14971 Second Edition 2007-03-01 Medical Devices – Application Of Risk Management To Medical Devices

IEC 62133 Edition 2.0 2012-12 Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes – Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From them, For Use In Portable Applications [Including: Corrigendum 1 (2013)]

UN/DOT 38.3 Edition 2 2017 Recommendations On The Transport of Dangerous Goods, Lithium Batteries

FDA Guidance Documents Utilized:

Radiation Safety Considerations for X-ray Equipment Designed for Hand-Held Use, issued December 24, 2008

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 11, 2005

Pediatric Information for X-ray Imaging Device Premarket Notifications, issued May 10, 2012

Content of Premarket Submissions for Management of Cybersecuirty in Medical Devices, issued October 2, 2014

FDA Battery Guidance Draft, dated January 1, 1994

Clinical Performance Data:

Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on this product.

Conclusion as to Substantial Equivalence:

Based on a comparison of intended use, indications, technological characteristics, principle of operation, features and performance data, the KaVo NOMAD Pro 2 Handheld X-ray System is deemed to be substantially equivalent to the predicate device.