February 8, 2024

Shenzhen Xpectvision Technology Co., Ltd.
℅ Mr. Silver Cai
Regulatory Affairs Manager
B507, Block A&B, Nanshan Medical Device Industrial Park,
Nanhai Avenue 1019, Nanshan District,
SHENZHEN, GUANGDONG 518000
CHINA

Re: K233914
Trade/Device Name: XVbeam2000
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: December 12, 2023
Received: December 12, 2023

Dear Mr. Cai:

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.

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 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)*
K233914

Device Name
XVbeam2000

Indications for Use *(Describe)*

The Handheld Dental X-ray System, model XVbeam2000, is indicated for use only by a trained and qualified dentist or dental technician as an extraoral X-ray source to produce diagnostic X-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

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.

Attachment 27 510(k) Summary

510 (k) Summary - K233914

(As Required by 21 CFR 807.92)

1. Date Prepared

December 12, 2023

2. Submitter's Information

Company Name:	Shenzhen Xpectvision Technology Co., Ltd.
Company Address:	B507, Block A and B, Nanshan Medical Device Industrial Park, Nanhai Avenue 1019, Nanshan District, Shenzhen City, Guangdong Province, China.
Contact Person:	Silver Cai
Phone:	(+86) 0755-26897621
Email:	ra@xpectvision.com

3. Trade Name, Common Name, Classification

Trade/Model Name:	XVbeam2000
Common Name:	Handheld Dental X-ray System
Classification Name:	Extraoral source x-ray system
Regulation Number:	21 CFR 872.1800
Product Code:	EHD
Device Class:	Class II

4. Identification of Predicate Device(s)

The identification predicates within this submission are as follows:

Manufacturer:	Aribex/ KaVo Dental Technologies, LLC
Trade/Model Name:	KaVo NOMAD Pro 2 Handheld X-ray System
Regulation Number:	21 CFR 872.1800
Product Code:	EHD
Classification Name:	Extraoral source x-ray system
FDA 510 (k) #:	K173319
Device Class:	Class II

5. Description of the Device

The subject device Handheld Dental X-ray System, model XVbeam2000, is a battery-operated, portable extraoral X-ray source system that is designed to generate X-rays to produce diagnostic quality intraoral X-ray images utilizing intraoral image receptors. The device can be used with three receptor types: film, digital intraoral X-ray sensors, and phosphor plates.

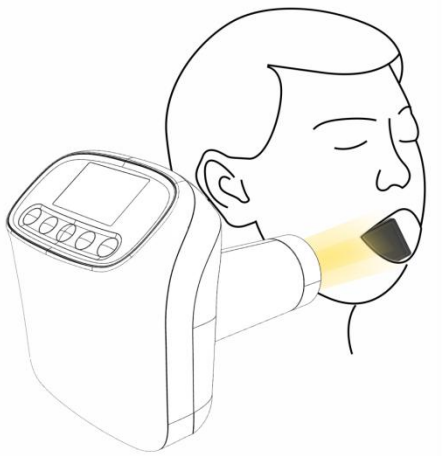


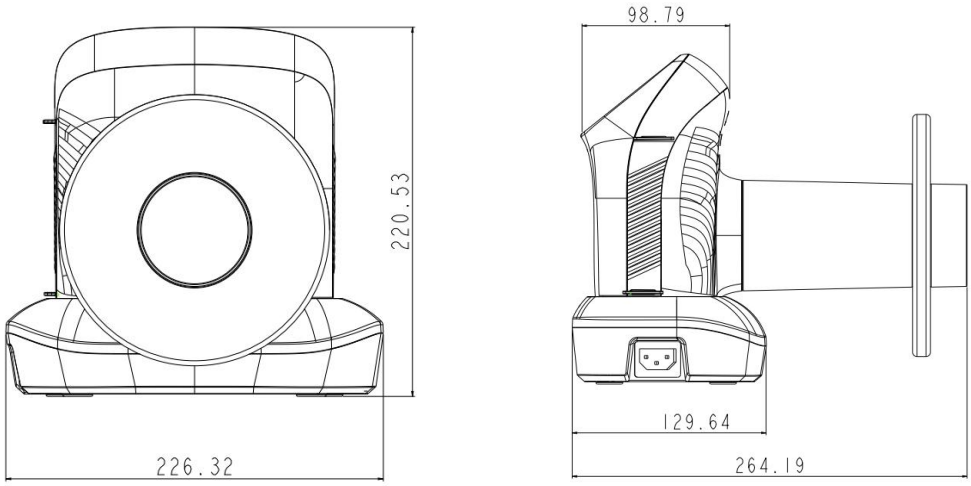
Figure 1. X-ray being generated by the XVbeam2000 during intraoral X-ray imaging

Note: image receptor is NOT part of the subject device

The subject device is designed for use in a dental office or similar environments (hospital ward etc.) where appropriate safeguards are implemented.

The subject device XVbeam2000 is an X-ray device with a DC generator. The handheld device features a main body (X-ray tube head), rechargeable battery (handset), charger, and charger AC/DC power supply. 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. The power is supplied by a rechargeable Lithium-Ion battery core pack built into a handset. This facilitates portability of the device.

Figure 2. The left is photo of main body and beam-limiting cone of the device; and the right is the photo of charger.



(a) Front view (b) Lateral view

Figure 3. Physical dimension of the device from two different views, the unit is in millimeter (mm).

To make the system as simple as possible for the operator, XVbeam2000 uses a fixed tube voltage of 65kV and a fixed tube current of 2.6mA. 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 (65 kV) and current (2.6 mA) are fixed with the exposure time varying based on patient type, receptor type, and anatomical feature. Exposures can be completed using the trigger.

Figure 4. Control panel and the display of the subject device; exposure time is pre-set depending on patient size, tooth group, and image receptor type. The exposure time can be adjusted by pressing the +/- buttons.

6. Indications For Use

6.1 Indications for use

The Handheld Dental X-ray System, model XVbeam2000, is indicated for use only by a trained and qualified dentist or dental technician as an extraoral X-ray source to produce diagnostic X-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

6.2 Suitable patient

General population (excluding pregnant women) who are evaluated by the dentist to need intraoral X-ray imaging examination.

7. Comparable Technological Characteristics

Characteristics	Predicate Device	Subject Device
Trade/Model Name	KaVo NOMAD Pro 2 Handheld X-ray System	XVbeam2000
510(k) Number	K173319	/
Regulation Name	Extraoral Source X-ray System	Same
Classification Name	unit, x-ray, extraoal with timer	Same
Common Name	Portable X-ray System	Handheld Dental X-ray System
Product Code	EHD	Same
Regulation Number	21 CFR 872.1800	Same
Review Panel	Radiology	Same
Regulation Medical Specialty	Dental	Same
Classification	II	Same
Indication 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 extraoal diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.	The Handheld Dental X-ray System, model XVbeam2000, is indicated for use only by a trained and qualified dentist or dental technician as an extraoral X-ray source to produce diagnostic X-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.
Intended user group	Trained and qualified dentist or dental technician	Same
Contact body site	The device does NOT directly contact with human body/organ. Note: When used clinically, barriers, such as clear plastic	Same

Characteristics	Predicate Device	Subject Device
	wrap, are used to isolate equipment from direct contact. Barriers should be changed after each patient. The protective barrier is disposable, and is NOT a part of this device.	
Patient populations	General population (excluding pregnant women) who are evaluated by the dentist to need intraoral X-ray imaging examination.	Same
Appearance		
Dimension	279.4mm x 266.7mm x 139.7mm	226.32mm x 220.53mm x 129.64mm
Weight	2.7kg	2.1kg
Display	LCD panel Display	Same
User Interface	Up-down buttons for exposure time selection, with timer display. Additionally, several user-selectable preset times with patient size, image-receptor type, and tooth selection icon on an LCD display.	Same
Source to skin distance	21 cm	20 cm
Cone diameter	60mm	Same
Backscatter radiation protection	6.75" dia. Pb-filled acrylic plastic scatter shield	6.38" dia. Pb-filled acrylic plastic scatter shield

Characteristics	Predicate Device	Subject Device
Exposure switch	Trigger on handset	Exposure trigger at front cover
Tubehead mounting	Monoblock and Handheld	Same
X-ray Monoblock	X-ray Tube Model: KL11-0.4-70(Hangzhou Kailong)	Same
	Stationary Anode Focus: 0.4 mm	Same
	Target Angle: 12°	Same
	Minimum permanent filtration: 1.5 mm Al (inherent filtration: 0.8mm glass, 0.5mm Al, 0.2mm plastic cap)	Minimum permanent filtration: 1.8 mm Al (inherent filtration: 0.8mmAl)
	Tube Voltage: 60 kV fixed	Tube Voltage: 65 kV fixed
	Tube Current: 2.5 mA fixed	Tube Current: 2.6 mA fixed
Exposure Time Range	0.02-1.0 seconds	0.01-2.0 seconds
Leakage radiation	<0.25mGy /h at 1 meter	Same
Energy Source	Rechargeable 21.6 V DC Lithium-ion battery core pack	Rechargeable 22.2V DC Lithium-ion polymer battery pack
Battery type	Rechargeable	Same
Casing	Hard shell case	Same
Connection method	Connector within handset enclosure	Connector within base plate enclosure
Waveform	Constant Potential (DC)	Same
Duty Cycle	1:60	1:30
EMI Coating	Copper	Same
Electrical Safety Standards	AAMI ES60601-1:2005/(R)2012 And A1:2012	Same

Characteristics	Predicate Device	Subject Device
EMI Standards	IEC60601-1-2 Ed. 4	IEC60601-1-2 Ed. 4 IEC/TR60601-4-2
Performance Standard	21 CFR 1020.30,1020.31; IEC60601-1-3; IEC60601-2-65	Same
Operation Conditions	Temperature: 10 to 40℃	Temperature: 10 to 40℃
	Humidity: 30 to 80% (Non-Condensing)	Humidity: 30 to 75%
	Atmospheric pressure: 80 to 106 kPa	Atmospheric pressure: 70 to 106 kPa
Storage and Transportation Conditions	Temperature: -20 to 50℃	Temperature: -20 to 55℃
	Humidity: <90% (Non-Condensing)	Humidity: 10 to 93% (Non-Condensing)
	Atmospheric pressure: 80 to 106 kPa	Atmospheric pressure: 70 to 106 kPa

8. Non-clinical Performance Testing

Non-clinical testing, (integration and functional) including phantom tests were conducted for the subject device during product development. The general purpose of each tests is to verify and validate the performance and functionality of the subject device.

System Verification testings include:

- System Integration Test (functional)
- Functionality verification

System Validation testings include:

- Acceptance test (workflow and user manual test)
- Legal and Regulatory test

Testing covers all related aspects that contribute to the device performance and functions. The test specification and acceptance criteria are related to the corresponding requirements. The test results show that all of the performance specifications have met the acceptance criteria. Verification and validation testing of the device was found acceptable to support the claim of substantial equivalence.

A list of FDA-recognized consensus standards and general guidance documents considered for testing the subject device is listed as follows:

1) FDA-recognized consensus standards

- IEC 60601-1:2005+CORR. 1:2006+CORR.2:2007+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC/TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical system.
- 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 60601-2-65 Edition 1.1 2017-05 CONSOLIDATED VERSION Medical electrical equipment - Part 2-65: Requirements for the basic safety and essential performance of dental intraoral X-ray equipment.

2) FDA Guidance Documents

- Electronic Submission Template for Medical Device 510(k)

Submissions: Guidance for Industry and Food and Drug Administration Staff, issued October 2, 2023

- User Fees and Refunds for Premarket Notification Submissions (510(k)s): Guidance for Industry and Food and Drug Administration Staff, issued October 2, 2022
- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices: Guidance for Industry and Food and Drug Administration Staff, issued September 14, 2018
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]: Guidance for Industry and Food and Drug Administration Staff, issued July 28, 2014
- Device Labeling Guidance #G91-1 (Blue Book Memo), issued March 8, 1991
- Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203), issued September 1, 1989
- Guidance on Medical Device Patient Labeling: Final Guidance for Industry and FDA Staff, issued April 19, 2001
- Electromagnetic Compatibility (EMC) of Medical Devices: Guidance for Industry and Food and Drug Administration Staff, issued June 6, 2022
- Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff, issued December 20, 2019
- Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff, issued June 14, 2023
- Radiation Safety Considerations for X-ray Equipment Designed for Hand-Held Use, issued December 24, 2008
- Definition of General Purpose Radiographic X-Ray System - 21 CFR

1020.30(b), issued March 1, 2005

- Pediatric Information for X-ray Imaging Device Premarket Notifications, issued November 28, 2017
- Guidance for Medical X-ray Imaging Devices Conformance with IEC Standards: Guidance for Industry and Food and Drug Administration Staff, issued February 21, 2023
- Performance Standard for Diagnostic X-Ray Systems and Their Major Components (21CFR 1020.30, 1020.31, 1020.32, 1020.33); Small Entity Compliance Guide, issued February 22, 2023
- Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff, issued February 3, 2016

9. Electrical Safety and EMC Testing

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the subject device in accordance with the following standards or guide document(s):

- IEC 60601-1:2005+CORR. 1:2006+CORR.2:2007+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- Electromagnetic Compatibility (EMC) of Medical Devices: Guidance for Industry and Food and Drug Administration Staff.

10. Software

The subject device incorporates embedded software. Tests are conducted for all software components developed in product development and for the complete product itself. The testing supports that all software specifications have met the acceptance criteria. Testing for verification and validation support the claims of substantial equivalence.

In accordance with "Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff", the software documentation is also included in this submission that covers the following aspects:

- Software description
- Software hazard analysis
- Software requirements specifications
- Software architecture design chart
- Software design specifications
- Software traceability analysis
- Software development environment description
- Verification & Validation testing
- Revision level history
- Unresolved anomalies

This software involved in the subject device is only the embedded software that is used as the control software. The embedded software does NOT involve the information exchange with the hospital information system or platform, nor it supports the functionality of internet connection.

11. Biocompatibility Information

The subject device does NOT contact directly with human body or organ, hence no biocompatibility testing was performed.

12. Sterility Information

No sterility testing was accomplished, as this device is not delivered sterile, nor does it require sterility.

13. Clinical Testing

Clinical data is NOT required for a finding of substantial equivalence.

14. Conclusion

As discussed above, the subject device Handheld Dental X-ray System, model XVbeam2000, employ the same fundamental technology and has a set of same or similar technological characteristics as the predicate device. The non-clinical data supports the safety of the device. The hardware and software verification and validation demonstrates that the subject device should perform as intended in the specified use conditions. The data included in this submission demonstrates that the subject device performs comparably to the predicate device currently marketed for the same intended use. The differences between the subject device and predicate device do not raise different questions of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.