February 17, 2022

Shenzhen Xpectvision Technology Co., Ltd.
℅ Mengsi Peng
Regulatory Affairs Manager
B507, Block A and B, Nanshan Medical Device Industrial Park,
Nanhai Avenue 1019, Nanshan District
Shenzhen, Guangdong 518067
CHINA

Re: K220277
Trade/Device Name: XVD2121 Plus, XVD2530
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: January 17, 2022
Received: January 31, 2022

Dear Mengsi Peng:

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,

Laurel Burk
Assistant Director
Diagnostic X-ray Systems Team
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K220277

Device Name
XVD2121 Plus, XVD2530

Indications for Use *(Describe)*
The digital intraoral X-ray sensors XVD2121 Plus, XVD2530 are intended for any dental practice that uses X-ray equipment for intraoral diagnostic purposes. Each can be used by trained dental professionals for patients receiving intraoral X-ray examinations and produces digital images that can be displayed and archived digitally.

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.

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Section 5 510(k) Summary

K220277

510 (k) Summary

K220277

(As Required by 21 CFR 807.92)

1. Date Prepared

January 17, 2022

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:	Mengsi Peng
Phone:	(+86) 0755-26897621
Email:	msp1022@xpectvision.com

3. Device/Trade Name, Common Name, and Classification Name

Device/Trade Name:	XVD2121 Plus, XVD2530
Common Name:	intraoral X-ray sensor
Classification Name:	Extraoral Source X-Ray System
Regulation Number:	21 CFR 872.1800
Product Code:	MUH
Device Class:	Class II

4. Identification of Predicate Device(s)

Relevant information of predicate device within this submission are as follows:

Manufacturer:	Schick Technologies Inc
Device/Trade Name:	Computed Oral Radiology System
Regulation Number:	21 CFR 872.1800
Product Code:	MUH
Classification Name:	Extraoral source x-ray system
FDA 510 (k) #:	K072134
Device Class:	Class II

5. Indications for Use

The digital intraoral X-ray sensors XVD2121 Plus, XVD2530 are intended for any dental practice that uses X-ray equipment for intraoral diagnostic purposes. Each can be used by trained dental professionals for patients receiving intraoral X-ray examinations and produces digital images that can be displayed and archived digitally.

6. Description of the Device

The subject device digital intraoral X-ray sensor, XVD2121 Plus or XVD2530, is used as X-ray receptor to acquire dental X-ray radiographic images in clinical entities. The subject device doesn't emit X-rays. The X-rays are to be generated from X-ray dental machine, a separate device. The subject device can be used by trained dental professionals for patients receiving intraoral X-ray imaging examinations and produces digital images that can be displayed, and archived digitally. To acquire X-ray intraoral radiographic image, first the X-rays are to be generated from the X-ray dental machine and passing through human teeth and surrounding anatomy; then the attenuated X-ray beams are detected by the sensor and subsequently converted into digital data that are to be transmitted to the software (computer). The imaging data are then stored in DICOM format images that can be displayed on the monitor and viewed by dentists.

The subject device digital intraoral X-ray sensor consists of sensor, adaptor, cable, and software (computer or laptop NOT part of the device), as shown in Fig.1.

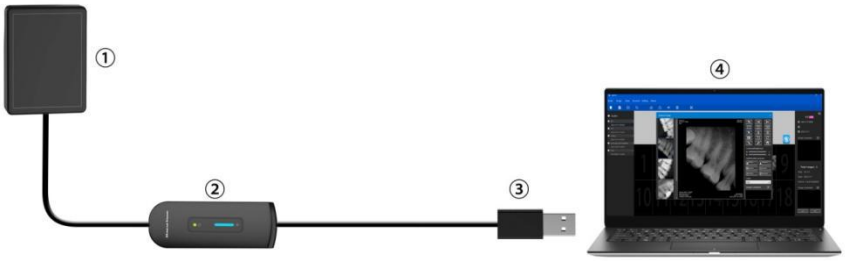


Figure 1. Components of the device

The intraoral sensor detects the incident X-rays and converts X-rays into digital signal or data. The sensor consists of tiny silicon chip-based pixels and their associated electronics encased in a plastic housing. The intraoral sensor is small, thin, flat, rigid rectangular box (as denoted ① in Fig.1), usually black in color and similar in size to intraoral film packets. Sensors vary in thickness from about 5 to 7 mm. Sensor is cabled to allow data to be transferred directly from the mouth to the computer (software) via the USB port.

Figure 2. Sensor inside a protective plastic sheath

When used clinically the sensor shall be covered with a protective plastic barrier envelope for infection control purposes. New sheath is required for each new patient and must be disposed of after patient use. One usually slide the sensor into the sheath to provide a secure barrier around the sensor (as shown in Fig. 2). The protective cover sheath is disposable and is a separate device, NOT a part of this device.

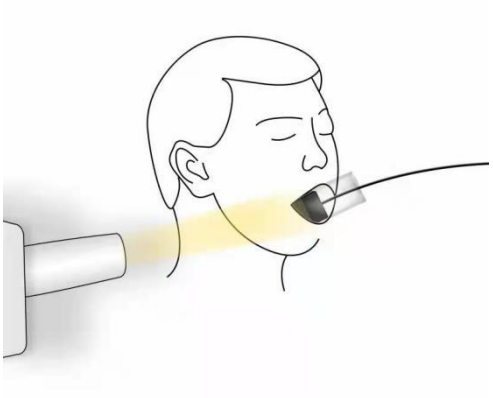
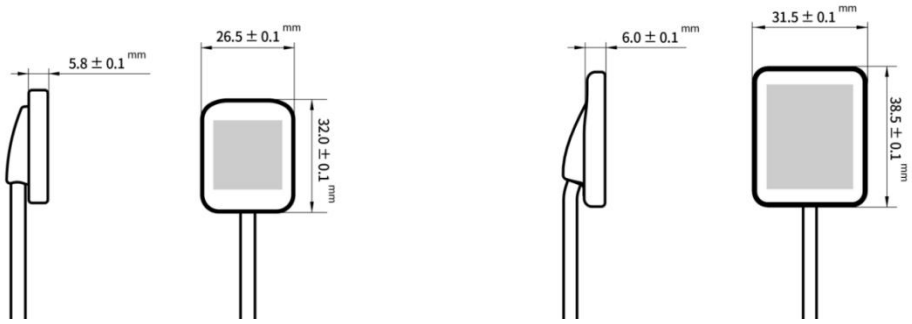


Figure 3. Placement of sensor (with sheath) during intraoral X-ray imaging

To acquire the intraoral X-ray radiographic images, the sensor (with sheath) is placed inside the mouth as X-ray receptor. First the X-rays are to be generated from the dental X-ray generating machine outside of the mouth (as shown in Fig. 3). The X-rays pass through and are attenuated by tooth/teeth and surrounding anatomy; the attenuated X-rays are detected by the sensor and then converted into digital data that are to be transmitted to the software (computer).

The digital data are then stored in DICOM format image that can be displayed on the monitor and viewed by dentists. The key clinical feature of intraoral sensor is the rapid availability of the image after exposure. The sensor is utilized as X-ray receptor, and does NOT emit X-rays. The X-ray generating equipment is a separate device, NOT a part of subject device.



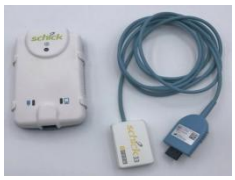
(a) Model XVD2121 Plus (b) Model XVD2530

Figure 4. Lateral and frontal view of the sensor
(the shaded region denotes effective imaging area)

The physical size of model XVD2530 is 31.5mm * 38.5mm, while that of model XVD2121 Plus is 26.5mm * 32mm. The effective imaging area of model XVD2530 is 29.5mm * 24.6mm, while that of model XVD2121 Plus is 20.0mm * 19.8mm. The differences between model XVD2121 Plus and model XVD2530 are the physical sizes and effective imaging areas. Otherwise model XVD2121 Plus and model XVD2530 are exactly same device. Different size is offered to better fit with size of oral cavity of individual patient and different anatomic region, such as posterior teeth or anterior teeth.

7. Comparable Technological Characteristics

Description	Predicate Device	Subject Device
Device/Trade name	Computed Oral Radiology System	XVD2121 Plus, XVD2530
510(K) number	K072134	K220277
Classification name	Extraoral Source X-ray System	Same
Product code	MUH	Same
Regulation number	21 CFR 872.1800	Same
Panel	Radiology	Same
Classification	II	Same
Indications for use	The Computed Oral Radiology System is indicated for patients undergoing an intra-oral dental x-ray examination. It produces instant, digital, intra-oral images of a patient's mouth while reducing the necessary x-ray dosage.	The digital intraoral X-ray sensors XVD2121 Plus, XVD2530 are intended for any dental practice that uses X-ray equipment for intraoral diagnostic purposes. Each can be used by trained dental professionals for patients receiving intraoral X-ray examinations and produces digital images that can be displayed and archived digitally.
Intended user group	Trained dental professionals	Same

Description	Predicate Device	Subject Device
Device components	 sensor, adaptor, cable, and USB connector.	XVD2121 Plus  same
		XVD2530  same
Sensor area	Size 1: 23.6mm x 31.9mm Size 2: 25.4mm x 38.3mm Size 3: 31.2mm x 43.0mm	XVD2121 Plus: 26.5mm x 32mm
		XVD2530 31.5mm x 38.5mm
Effective imaging area	Size 1: 18mm x 24mm Size 2: 20mm x 30mm Size 3: 25.6mm x 36mm	XVD2121 Plus: 20.0mm x 19.8mm
		XVD2530: 24.6mm x 29.5mm
Deployment methods where relevant	Covered with a protective sheath then placed inside the mouth.	Same

Description	Predicate Device	Subject Device
Contact body site	The device does not directly contact with human body or organ. Note: When used clinically the sensor shall be covered with a protective plastic barrier envelope for infection control purposes and then placed inside the mouth during imaging procedure. The protective cover sheath is disposable and is a separate device, NOT a part of this device.	Same
Patient populations	General population (excluding pregnant women) who are evaluated by the dentist to need intraoral X-ray imaging examination.	Same
Installation type	Portable	Same
Sensor structure	Scintillator + CMOS	Semiconductor + CMOS ASIC
Actual spatial resolution	7 lp/mm	Same
Low contrast resolution	The imaging can distinguish 1mm - diameter hole on aluminum plates	Same
Image non-uniformity	≤ 2%	Same

Description	Predicate Device	Subject Device
Ghost and artifact	No	Same
Gray scale	12 bit	16 bit
Power consumption	5V DC, 250mA	5V DC, 100mA
Communications	USB 2.0	Same
Cooling	Ambient air cooling	Same
Protection against matter/water	IP68	IP67
Protection against shock	Type BF applied part	Same
Operation environment	Temperature: 10 to 40°C Humidity: ≤ 75% (Non-Condensing) Atmospheric pressure: 700hPa ～ 1060hPa	Temperature: 10 to 40°C Humidity: ≤ 80% (Non-Condensing) Atmospheric pressure: 700hPa ～ 1060hPa
Storage and Transportation environment	Temperature: -40 to 70°C Humidity: 10 to 100% (Non - Condensing) Atmospheric pressure: 500hPa ～ 1060hPa	Temperature: -20 to 55°C Humidity: ≤ 93% (No condensation) Atmospheric pressure: 700hPa ～ 1060hPa
Software	Zoom Window	XVDental
Standards Compliance	IEC 60601-1:2005+A1:2012 IEC 60601-1-2:2014	IEC 60601-1:2005+A1:2012 IEC 60601-1-2:2014 IEC 60601-2-65:2017

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 Validation testings include:

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

System Verification testings include:

- System Integration Test (functional)
- Functionality verification
- Image Quality (IQ) Evaluation

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 61223-3-4 First edition 2000-03 Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests – Imaging performance of dental X-ray.
- 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

- FDA Guidance for the Medical X-Ray Imaging Devices Conformance with IEC Standards.
- FDA Guidance for the 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)].
- FDA Guidance for the Device Labeling #G91.
- FDA Guidance for the Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically - Powered Medical Devices.
- FDA Guidance for the Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions.

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.
- FDA Guidance for the Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically - Powered Medical Devices.

10. Software and Cybersecurity

The subject device is a hardware-based device that incorporates 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 "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", 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

The submitter conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from the subject device to an external recipient.

Cybersecurity information in accordance with guidance document "Content of Premarket Submissions for Management of Cybersecurity Medical Devices," is discussed in associated Cybersecurity documentation.

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, either model XVD2121 Plus or model XVD2530, employs 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.