June 11, 2026

Changzhou Boen Zhongding Medical Technology Co., Ltd.
℅ Shuo Huang
Regulatory Affairs Specialist
1st to 2nd Floor, South west Side of Building B1, NO.9
Changyang Road, West Taihu Science and Technology Industrial
Changzhou, JS 213100
CHINA

Re: K250839
Trade/Device Name: Dental X-ray System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: March 17, 2025
Received: March 20, 2025

Dear Shuo Huang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250839

Device Name
Dental X-ray System

Indications for Use *(Describe)*
The Dental X-ray System is a digital, extra-oral imaging system with panoramic, cephalometric, and tomographic capabilities, designed to:
a. Produce orthopantomographic images of the maxillofacial region.
b. Generate radiographs of the jaws, parts of the skull, and carpus for cephalometric examination, if equipped with a CEPH arm.
c. Produce tomographic images of the head, including the ear, nose, and throat (ENT), the dentomaxillofacial complex, teeth, mandible, maxilla, temporomandibular joint (TMJ), and other areas of the human skull and neck, including sections of the cervical spine, for diagnostic support.
If equipped with a Dental X-ray Unit, The Dental X-ray Unit is an extra-oral x-ray source for producing diagnostic dental radiographic examination and diagnosis of teeth, jaw, and other oral structures using intra-oral image receptors (intra-oral image receptors is not included in our Dental X-ray System).
The device is operated and used by physicians, dentists, radiologic technologists, and other qualified 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.

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K250839

510(K) Summary

As required by 21 CFR Part 807.92

1. Date Prepared [21 CFR 807.92(a)(1)]

June 7,2026

2. Submitter's Information [21 CFR 807.92(a)(1)]

Name:	Changzhou Boen Zhongding Medical Technology Co., Ltd.
Address:	1st to 2nd Floor, South west Side of Building B1, NO.9 Changyang Road, West Taihu Science and Technology Industrial Park, Changzhou, Jiangsu, 213100 China
Contact person:	Shuo Huang
Title:	Regulatory Affairs Specialist
E-mail:	huang.shuo@bondent.com
Tel:	+86-13913615957

3. Identification of subject device [21 CFR 807.92(a)(2)]

510(K) number:	K250839
Trade/Device Name:	Dental X-ray System
Common name:	x-ray, tomography, computed, dental
Regulation Number:	892.1750
Regulation Name:	Computed tomography x-ray system
Regulation Class:	Class 2
Panel:	Radiology
Product Code:	OAS

4. Identification of predicate Device [21 CFR 807.92(a)(3)]

510(K) number:	K212254
Trade/Device Name:	DENTRIα series
Common name:	x-ray, tomography, computed, dental
Regulation Number:	892.1750
Regulation Name:	Computed tomography x-ray system
Regulation Class:	Class 2
Panel:	Radiology
Product Code:	OAS

510(K) number:	K223058

Trade/Device Name:	EzRay Air 2 Wall (Model: VEX-S350W)

Common name:	unit, x-ray, extraoral with timer
Regulation Number:	872.1800
Regulation Name:	Extraoral source x-ray system
Regulation Class:	Class 2
Panel:	Radiology
Product Code:	EHD

5. Device Description [21 CFR 807.92(a)(4)]

The Dental X-ray System is a panoramic, cephalometric (Optional), cone beam computed tomography and dental radiograph (Optional) device. It can

- producing tomographic images of the oral and maxillofacial region, for diagnostic examination of dentition (teeth), jaws, oral structures and some cranial bones.
- produce panoramic X-ray images for diagnostic examination of dentition (teeth), jaws and oral structures;
- produce radiographs of maxillofacial region and parts of the skull for cephalometric examination, if equipped with CEPH.
-produce diagnostic dental radiographs for the treatment of diseases of the teeth, jaw, and other oral structures using intra-oral image Receptors (intra-oral image receptors are not included in our Dental X-ray System), if equipped with dental X-ray Unit.

The Dental X-ray System is composed of Column, assembled mobile group, rotation arm, CEPH arm, control panel.

The Column is the main vertical support structure of the CBCT system. It provides stability and serves as the foundation to which other components. It can raise the whole assembled mobile group of the device to ensures the positioning and height adjustment of the system to accommodate patients of different sizes.

The assembled mobile group is movable parts of the CBCT system that can be raised by the column, it is the motorized components that enable the movement of the rotation arm and the patient positioning system. It provides flexibility in positioning the patient.

The rotation arm is responsible for the circular motion around the patient’s head, allowing the CBCT system to capture multiple images from different angles. These images are then reconstructed into a 3D image.

The CEPH arm is a dedicated component for taking cephalometric X-rays, it captures 2D images of the patient’s head from lateral (side) views.

The control panel is the user interface of the CBCT system, where the operator can set image mode, move the mobile column, turn the positioning lasers on and off, and Control Rotation arm reset.

Additionally, in model Bondream 3D-1030Pro (config 3), a wall-mounted Dental X-ray Unit (model:

Bondream 2000) is included, which is an imaging device specially used to photograph teeth and their surrounding structures.

1) Configurations

	X-Ray Generator	CT/Pano Detector	CEPH Detector	Dental X-ray Unit
Bondream 3D-1030Pro (config 3)	Bon-1000D	Jupi0606X1	Pluto0900X1	Bondream 2000
Bondream 3D-1030Pro (config 6)	Bon-1000D	Jupi0606X1	Without	Without
Bondream 3D-1030Pro (config 8)	Bon-1000D	Jupi0606X1	Pluto0900X1	Without
Bondream 3D-1030X2	Bon-1000DR	CareView 300RF	CareView750L	Without
Bondream 3D-1030X3	Bon-1000DR	CareView 300RF	Without	Without

2) Description of the image detectors used.

	CT/Pano Detector		CEPH Detector	
Detector model	Jupi0606X1	CareView 300RF	Pluto0900X1	CareView 750L
Manufacturer	iRay	CareRay	iRay	CareRay
Detector type	Flat panel, CsI+TFT, CsI/GOS	Flat panel, CsI+IGZO+TFT	Flat panel, CsI+CMOS+TFT	Flat panel, CsI+ a-Si +TFT
Resolution (pixels)	1536x1536	1536x2048	2252×68	2560×2048
Pixel size（um）	100	98	100	120
MTF	56%@1lp/mm	60%@1lp/mm	100%@0lp/mm	70%@1lp/mm
DQE	62%@0lp/mm	70%@0.5lp/mm, 2uGy	/	70%@0lp/mm
Active area (mm)	153.6x153.6	150.0x200.0	225.2×6.8	307.2×244.3
A/D Conversion	16 bits	16 bits	16 bits	16 bits

6. Indication for Use [21 CFR 807.92(a)(5)]

The Dental X-ray System is a digital, extra-oral imaging system with panoramic, cephalometric, and tomographic capabilities, designed to:

a. Produce orthopantomographic images of the maxillofacial region.

b. Generate radiographs of the jaws, parts of the skull, and carpus for cephalometric examination, if equipped with a CEPH arm.

c. Produce tomographic images of the head, including the ear, nose, and throat (ENT), the dentomaxillofacial complex, teeth, mandible, maxilla, temporomandibular joint (TMJ), and other areas of the human skull and neck, including sections of the cervical spine, for diagnostic support.

If equipped with a Dental X-ray Unit, The Dental X-ray Unit is an extra-oral x-ray source for producing diagnostic dental radiographic examination and diagnosis of teeth, jaw, and other oral structures using intra-oral image receptors (intra-oral image receptors is not included in our Dental X-ray System).

The device is operated and used by physicians, dentists, radiologic technologists, and other qualified professionals.

7. Determination of Substantial Equivalence

Summary of technological characteristics of the device compared to the predicate device. [21 CFR 807.92(a)(6)]

Compared to the predicate devices, the subject device has the similar indication for use, same technical principle, similar performance specification, same safety as the predicate device, the summarized comparison information is listed in the following table

SE Comparisons	**Subject Devices**		**Predicate Device**	**Similarities /Differences**
	Bondream 3D-1030Pro (config 3) **Bondream 3D-1030Pro (config 6)** **Bondream 3D-1030Pro (config 8)**	**Bondream 3D-1030X2** **Bondream 3D-1030X3**	**DENTRIα series**	
510(k) Number	K250839	K250839	K212254	/
Common/Usual Name	x-ray, tomography, computed, dental	x-ray, tomography, computed, dental	x-ray, tomography, computed, dental	/
Regulation Number	892.1750	892.1750	892.1750	/
Product Code	OAS	OAS	OAS	/
Class	Class II	Class II	Class II	/
Indications for Use	The Dental X-ray System is a digital, extra-oral imaging system with panoramic, cephalometric, and tomographic capabilities, designed to: a. Produce orthopantomographic images of the maxillofacial region. b. Generate radiographs of the jaws, parts of the skull, and carpus for cephalometric examination, if equipped with a CEPH arm.	The Dental X-ray System is a digital, extra-oral imaging system with panoramic, cephalometric, and tomographic capabilities, designed to: a. Produce orthopantomographic images of the maxillofacial region. b. Generate radiographs of the jaws, parts of the skull, and carpus for cephalometric examination, if equipped with a CEPH arm.	The DENTRIα series is a Computed Tomography X-Ray imaging device specialized in diagnosing general dental treatments and orthodontic purpose using Panoramic and Cephalometric images respectively. In addition DENTRIα series is used in the field of Otolaryngology by capturing 360	similar

	c. Produce tomographic images of the head, including the ear, nose, and throat (ENT), the dentomaxillofacial complex, teeth, mandible, maxilla, temporomandibular joint (TMJ), and other areas of the human skull and neck, including sections of the cervical spine, for diagnostic support. If equipped with a Dental X-ray Unit, The Dental X-ray Unit is an extra-oral x-ray source for producing diagnostic dental radiographic examination and diagnosis of teeth, jaw, and other oral structures using intra-oral image receptors (intra-oral image receptors is not included in our Dental X-ray System). The device is operated and used by physicians, dentists, radiologic technologists, and other qualified professionals.	c. Produce tomographic images of the head, including the ear, nose, and throat (ENT), the dentomaxillofacial complex, teeth, mandible, maxilla, temporomandibular joint (TMJ), and other areas of the human skull and neck, including sections of the cervical spine, for diagnostic support. If equipped with a Dental X-ray Unit, The Dental X-ray Unit is an extra-oral x-ray source for producing diagnostic dental radiographic examination and diagnosis of teeth, jaw, and other oral structures using intra-oral image receptors (intra-oral image receptors is not included in our Dental X-ray System). The device is operated and used by physicians, dentists, radiologic technologists, and other qualified professionals.	degree rotation sequence of the head and neck areas, including the ENT and dentomaxillofacial areas for a dental treatment in adult and pediatric dentistry and obtains x-ray images from different angles and calculate through computer-processed to produce 3D xray tomographic images. The DENTRIα series used by physicians, dentists, and x-ray technologists.	
Operation Mode	CBCT Mode PANO Mode CEPH Mode(optional) Dental Mode(optional)	1. CBCT Mode 2. PANO Mode 3. CEPH Mode(optional)	1. CT 2. Panorama 3. Ceph 1) One-Shot type 2) Scan type 4. Model Scan	similar
X-ray generator	Bon-1000D	Bon-1000DR	PXD-140CT	different
X-ray tube	D-054SB	D-054SB	OPX/105 (C.E.I.)	different
Target angle	5°	5°	5°	same

Focal spot size	0.5mm	0.5mm	0.5 mm	same
Inherent filtration	0.8mm Al	0.8mm Al	0.5mm Al	same
Anode material	Tungsten	Tungsten	Tungsten	same
Total filtration	2.8mm Al	2.8mm Al	> 2.5 mmAl > 2.5 mmAl + 0.5 mmCu (Optional)	similar
Range of X-ray Tube Voltage	60kV-100kV	60kV-100kV	PXD-140CT (Optional) 1. CT 60-110 kV ±8% 2. Panorama 60-90 kV ±8% 3. Cephalo 1) One-Shot type 60-110 kV ±8% 2) Scan type 60-90 kV ±8%	similar
Range of X-ray Tube Current	4mA-10mA	4mA-10mA	4-10 mA ±10%	same
Range of Irradiation Time	8s,24s,36s (CBCT mode) 14s,9.6s (PANO mode) 14s,8.4s (CEPH mode)-- -applicable to Bondream 3D-1030Pro(config 3&8) 0.01s-2.0s, using R'10 numerical system (Dental X-ray Unit)-- -applicable to Bondream 3D-1030Pro(config 3)	8s,16s,20s (CBCT mode) 5s,9.6s ,12s,14s(PANO mode) 0.5s, 0.8s, 1.6s (CEPH mode)--applicable to Bondream 3D-1030X2	1. CT 8.0-36.0 s ± (5 % + 50 ms) 2. Panorama 1.2-14.0 s ± (5 % + 50 ms) 3. Cephalo 1) One-Shot type 0.5 s to 2.0 s ± (5 % + 50 ms) (in 0.5 s increments) 2) Scan type 2.5-8.0 s ± (5 % + 50 ms) 4. Model Scan 24 s	similar

Detector type	CBCT/PANO:Flat panel, CsI+TFT, CsI/GOS ; CEPH:Flat panel, CsI+CMOS+TFT	CBCT/PANO:Flat panel, CsI+TFT+IGZO; CEPH：Flat panel, Flat panel, CsI+ a-Si +TFT	1. CT CMOS or TFT:a-Si 2. Panorama CMOS or TFT:a-Si 3. Cephalo 1) One-shot type TFT:a-Se 2) Scan type CMOS	similar
Detector Pixel size （um）	100 um (CBCT/PANO/CEPH)	CBCT/PANO:100 um CEPH:120 um	1. CT 100.1 um or 119 um 2. Panorama 100.1 um or 119 um 3. Cephalo 1) One-shot type 129.0 um 2) Scan type 99.0 um	different
Active area(mm)	CBCT/PANO:153.6mm x153.6mm CEPH:225.2mm×6.8mm	CBCT/PANO:204.8mmx204.8mm CEPH:307.2mm×244.3mm	1. CT 131mm x 131mm or 149.464 mmx 149.464mm 2. Panorama 6mm x 130mm or 6mm x 149.5mm 3. Cephalo 1) One-shot type 198mm x 264mm 2) Scan type 6.7mm x 228mm	different
MTF	CBCT/PANO:56%@1lp/mm CEPH:100%@0lp/mm	CBCT/PANO:60%@1lp/mm CEPH:70%@1lp/mm	1. CT: - 57% at 1 lp/mm or - 60% at 1 lp/mm 2. Panorama: - 57% at 1 lp/mm or - 60% at 1 lp/mm 3. Cephalo 1) One shot type	different

			- 83.3% at 2 lp/mm 2) Scan type: - 65% at 1 lp/mm	
DQE	CBCT/PANO:62%@0lp/mm	CBCT/PANO:70%@0.5lp/mm,2uGy CEPH:70%@0lp/mm	1. CT: - 70% at 0 lp/mm or - 60% at 1 lp/mm 2. Panorama: - 70% at 0 lp/mm or - 60% at 1 lp/mm 3. Cephalo 1) One shot type - 38.5% at 0 lp/mm 2) Scan type: - 57% at 1 lp/mm	different
Source Image Distance	600mm (CBCT mode) 560mm (PANO mode) 1765mm (CEPH mode)	600mm (CBCT mode) 560mm (PANO mode) 1629mm (CEPH mode)	1. CT 600 mm 2. Pano 560 mm 3. Cephalo 1) One-Shot Ceph 1792 mm 2) Scan Ceph 1,782 mm	similar
Format Compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible	same

Substantial Equivalence Discussion

The Bondream 3D-1030Pro series and Bondream 3D-1030series are substantially equivalent to the predicate device identified above with respect to intended use, principles of operation, and technological characteristics. From the information provided in table above, it is understood that the subject device does not introduce any new technology and/or indications of use. Therefore, the Bondream 3D-1030Pro series and Bondream 3D-1030series are considered substantially equivalent to the predicate device.

SE Comparisons	Subject Devices	Predicate Device	Similarities/Differences
	Dental X-ray Unit of Bondream 3D-1030Pro (config 3)(Model:Bondream 2000)	**EzRay Air 2 Wall (Model: VEX-S350W)**	
510(k) Number	K250839	K223058	/
Common/Usual Name	Extraoral source x-ray system	Extraoral source x-ray system	/
Regulation Number	21 CFR 872.1800	21 CFR 872.1800	/
Product Code	EHD	EHD	/
Class	II	II	/
Intended Use	Dental X-ray Unit (Model:Bondream 2000) is intended to produce diagnostic dental radiographs for the treatment of diseases of the teeth, jaw, and other oral structures using intra-oral image receptors.	The EzRay Air 2 Wall (Model: VEXS350W) is a dental X-ray system intended for use by a trained and qualified dentist or dental technician for both adult and pediatric subjects for producing diagnostic dental radiographs for the treatment of diseases of the teeth, jaw, and other oral structures using intra-oral image receptors.	similar
Patient	adult and pediatric	adult and pediatric	same
Mechanical			
Minimum source to skin distance	200mm	200 mm	same
X-ray field Size	60mm round	60 mm round	same
Focal spot	0.4 mm	0.4 mm	same
Exposure time	0.01-2.0s	0.05 - 2.0 seconds	similar
Tube current	5mA	5mA	same
Tube	70kV	70 kV	same

voltage			
Electric Power Voltage	230VAC	AC 100-240 V	similar
Rated Current	8A	10 A	different

Substantial Equivalence Discussion

The Bondream 2000 is substantially equivalent to the predicate device identified above with respect to intended use, principles of operation, and technological characteristics. From the information provided in table above, it is understood that the subject device does not introduce any new technology and/or indications of use. Therefore, the Bondream 2000 is considered substantially equivalent to the predicate device.

8. Performance Data

Clinical test:

Subject assessed

5 clinical images (3000 diagnostic radiographic images) of the CBCT image (covering all listed anatomical regions),

5 clinical images Panoramic image (full dentition and jaw structure),

5 clinical images Panoramic image of the TMJ,and

5 clinical images Lateral cephalometric image

Acceptance criteria

PASS - Diagnostically Acceptable:

The image demonstrates sufficient spatial resolution, contrast resolution, and structural alignment to successfully fulfill all assigned diagnostic tasks. Minor non-systemic anomalies - including localized beam hardening or streak artifacts caused by the patient's own existing metallic restorations – are permissible only where they do not obliterate the primary regions of diagnostic interest and do not prevent formulation of a complete clinical diagnosis and treatment plan without supplemental imaging.

FAIL - Diagnostically Not Acceptable:

The image fails to meet the minimum threshold for clinical diagnostic utility due to severe artifact degradation, extreme motion blur, structural distortion or improper patient positioning. A FAIL is assigned when key anatomical landmarks or pathologies are completely obscured, when unacceptable geometric distortion is present, or when image quality would necessitate a mandatory retake in standard clinical practice.

Results

Metric	Count	Percentage
Total	3015	100%
Pass	2520	83.6%
Fail	495	16.4%
Of which - Device-Intrinsic Quality Failures(Resolution / Contrast only)	3	0.1%
Of which - Metal Artifact / Patient Motion / PositioningErrors	492	16.3%

Conclusion

The conclusion show that the clinical images provided support the safety and effectiveness of the device for its intended use.

9. Non-clinical data

The Bondream 3D-1030Pro series, Bondream 3D-1030series and Bondream 2000 are verified and validated according to the FDA design control requirements, 21 CFR 820. The subject device had been subjected to the applicable safety and performance testing before release to ensure the device meets all its specifications. The quality assurance measures applied to the design and development of the subject device include, but not limited to risk analysis, verification and validation, product specifications and design reviews.

1) Thermal, electrical, mechanical safety & Electromagnetic Compatibility

The Bondream 3D-1030Pro series, Bondream 3D-1030series and Bondream 2000 comply with the electrical safety and electromagnetic compatibility requirements established by the standards below:

-IEC 60601-1:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

-IEC 60601-1-3:2021 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

-IEC 60601-2-63:2021 Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment

-IEC 60601-2-65:2021 Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral-X-ray equipment

-IEC 60825-1:2007 Safety of laser products - Part 1: Equipment classification and requirements

-IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

2) Software Verification and Validation

Software information is provided in accordance with FDA guidance: “Content of Premarket Submissions for Device Software Functions, issued on June 14, 2023.”

Cybersecurity information is provided in accordance with FDA guidance: “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, issued on September 27, 2023”

3) Biocompatibility

Biocompatibility evaluation is provided in accordance with FDA guidance: “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", issued on: September 8, 2023”

Biocompatibility tests were conducted in accordance with

- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

-ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization

-ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation

4) Performance Test

Bench Testing were conducted for CBCT Imaging in accordance with IEC 61223-3-7: 2021 Evaluation and routine testing in medical imaging departments - Part 3-7: Acceptance and constancy tests - Imaging performance of X-ray equipment for dental cone beam computed tomography. In bench testing, spatial resolution, low-contrast resolution, image uniformity, voxel accuracy, and reconstruction efficiency were verified, the verification results show that the subject devices meet claims.

Bench Testing were conducted for 2D X-ray Imaging in accordance with FDA guidance: “Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices“. In bench testing, the physical characteristics, operational functions, functional characteristics, exposure characteristics and safety feature were verified, the verification results shows that the subject devices meet claims.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Dental X-ray System (Bondream 3D-1030Pro (config 3),Bondream 3D-1030Pro (config 6),Bondream 3D-1030Pro (config 8),Bondream 3D-1030X2,Bondream 3D-1030X3), are as safe, as effective, and performs as well as the legally marketed predicated device DENTRIα series (K212254).

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Dental X-ray Unit of Bondream 3D-1030Pro (config 3) (Model:Bondream 2000), is as safe, as effective, and performs as well as the legally marketed predicated device EzRay Air 2 Wall (Model: VEX-S350W) (K223058).