March 10, 2026

Cefla S.C.
℅ Ilenia Muccione
Regulatory Affairs Manager
Via Selice Provinciale 23/A
IMOLA (Bo), BO 40026
ITALY

Re: K252353
Trade/Device Name: myray ProXIma X6
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS, MUH
Dated: February 6, 2026
Received: February 9, 2026

Dear Ilenia Muccione:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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)*
K252353

Device Name
myray ProXIma X6

Indications for Use *(Describe)*
ProXIma X6 is an extra-oral X-ray equipment for digital panoramic, tomographic and cephalometric Xrays exams, indicated for the following:
(I) production of orthopanoramic images of the maxillofacial area, diagnostic dental exams on teeth, dental arches and other structures of the oral cavity;
(II) Production of X-ray images of the dental arches, parts of the cranium and of the carpus in support of cephalometric examination, where the configuration includes the CEPH arm;
(III) production of tomographic images of the structures of the maxillofacial area and oral cavity for diagnostic dental exams on teeth, dental arches, the structures of the oral cavity, where the configuration includes the CBCT option.
The device is operated and used by physicians, dentists, x-ray technologists and other legally 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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K252353

510(k) SUMMARY, AS REQUIRED BY CFR 807.92

Submitter's Name:	CEFLA S.C.
Address:	Via Selice Provinciale 23/a Imola, BO 40026 ITALY Tel. +39 0542 653111 Fax +39 0542 653444
Establishment Registration Number:	3006610845
Summary Preparation Date:	February 06th,2026
Contact Person:	Ilenia Muccione, Regulatory Affairs
Telephone Number:	+39 0542 653459
Email:	regulatory@cefla.it

Trade/Device name:	myray ProXIma X6
Classification Name:	Computed Tomography X-Ray System Classification Name: Computed Tomography X-Ray System Device Class: II Primary Product Code: OAS Secondary Product Code: MUH Regulation Number: 21 CFR §892.1750
Description:	The ProXIma X6 device, with its alternative proprietary names NewTom VG-One and EOS Compact is a panoramic (PAN, 2D), cephalometric (CEPH, 2D) and tomographic (CBCT, 3D) radiological system consisting of an X-ray system that acquires radiological images by rotating around the patient's head. The X-ray device consists of a rotating arm fitted on a column support for carrying out panoramic X-rays or tomographic examinations. The rotating arm is able to rotate and translate with motorized movements, allowing the X-ray generator and the image detector to move around the patient according to complex orbits that follow the morphological profile. The rotary arm is applied on a column support which can slide vertically through a motorized movement. The X-ray device can feature a cephalometric examination arm, fitted on the column support. The arm houses a cephalostat, which keeps the patient position during the exam, and the image detector which translates in synchronization with the X-ray source movement. User's choice, the X-ray device can be equipped with a single image detector (thus the operator must position it on the rotary arm for panoramic X-rays or on the cephalometric examination arm for tele-X-ray examinations - CEPH) or with two separate image detectors (which cannot be moved, one on the rotary arm and the other on the cephalometric examination arm). The device is a digital imaging equipment created to simplify the acquisition process for X-ray image, intended for use by qualified professionals in the field, which allows to obtain dental images. The image is acquired through the use of an X-ray detector and a constant-voltage X-ray source, powered by a high-frequency and high-voltage generator. The image is then transferred to a computer, either in real time (2D or 3D) or subsequently (2D) depending on the operator's selection and requirements.

The device is operated and used by physicians, dentists, X-ray technologists and other legally qualified professionals.

ProXIma X6 is an extra-oral X-ray equipment for digital panoramic, tomographic and cephalometric X-rays exams, indicated for the following:
1. production of orthopanoramic images of the maxillofacial area, diagnostic dental exams on teeth, dental arches and other structures of the oral cavity;
2. Production of X-ray images of the dental arches, parts of the cranium and of the carpus in support of cephalometric examination, where the configuration includes the CEPH arm;
3. production of tomographic images of the structures of the maxillofacial area and oral cavity for diagnostic dental exams on teeth, dental arches, the structures of the oral cavity, where the configuration includes the CBCT option.
The equipment performs tomographic examinations through the acquisition of X-ray images through a rotational sequence and the reconstruction of a three-dimensional matrix of the volume examined, producing two- and three-dimensional views of this volume. This technique is known as CBCT.
ProXIma X6 is a digital X-ray unit, suitable for professionals in the sector, allowing them to obtain dental imaging in a simple, automated manner. The image is acquired through the use of an X-ray detector and a constant-voltage X-ray source, powered by a high-frequency high-voltage generator. The image is then transferred to a computer in real time for subsequent processing.

ProXIma X6 allows the following acquisitions to be made:
- paediatric panoramic or standard views (PAN);
- complete or partial view of the teeth, selected by the user (DENT);
- frontal and lateral views of the maxillary sinus (SIN);
- lateral and posterior-anterior views of the temporomandibular joints (TMJ).

Where equipped with CEPH arm, ProXIma X6 offers the following projections:
- cephalographies in latero-lateral view, in different formats;
- cephalographies in anteroposterior and posteroanterior view;
- hand (carpus) X-ray.

If the configuration includes CBCT exams, ProXIma X6 also allows the acquisition of tomographic images.

The device belongs to the category of panoramic, cephalometric and tomographic equipment, and does not present any new technology or innovation with respect to products currently marketed by the CEFLA and considered as predicate and reference devices.
ProXIma X6 predicate device is hyperion X5 already cleared by the Agency in K200688. Compared to the reference device Hyperion X9 Pro, ProXIma X6 is not able to perform otorhinolaryngologic analysis: particularly, sensor dimensions are not able to support images of the ear, nose and throat (ENT) area, and other areas of the human skull and neck with sections of the cervical spine for use in diagnostic support.
ProXIma X6 apparatus consists of a rotary arm fitted on a column support for carrying out panoramic X-rays or tomographic examinations. The rotary arm features roto-translation motorized movements which allow moving X-ray emission system and image detector around the patient, according to complex orbits following the morphological profile. The rotary arm is applied on a column support which can slide vertically through a motorized movement.

	The configuration of ProXIma X6 device X-ray system consists of the main parts listed below: 1) Tomographic CBCT panel or Sensor for panoramic x-ray exams (alternatively) 2) Patient head support for panoramic and CBCT acquisitions 3) Arm for cephalometric x-ray exams (optional) 4) Sensor for cephalometric x-ray exams (optional) 5) Patient head support for cephalometric acquisitions (optional) 6) Handles for patient positioning 7) Laser pointers 8) X-ray source 9) Telescopic column (optional) 10) Stands for floor support (optional) The device must be used in conjunction with software for acquisition and management of 2D and 3D images. The software system is identified for simplicity by the name 'Neowise,' which corresponds to the name of the interface module and appears on the user interface screens. The software is installed on a general purpose Personal Computer and offers all the functions necessary to perform the exam (from movements control to X-ray acquisition), save images and patient's data, manage, process, view and share 2D and 3D images, which can be obtained either from the CEFLA device or from external sources, and provides import/export of images or reports in different standard formats.
Indication for Use:	ProXIma X6 is an extra-oral X-ray equipment for digital panoramic, tomographic and cephalometric Xrays exams, indicated for the following: (I) production of orthopanoramic images of the maxillofacial area, diagnostic dental exams on teeth, dental arches and other structures of the oral cavity; (II) Production of X-ray images of the dental arches, parts of the cranium and of the carpus in support of cephalometric examination, where the configuration includes the CEPH arm; (III) production of tomographic images of the structures of the maxillofacial area and oral cavity for diagnostic dental exams on teeth, dental arches, the structures of the oral cavity, where the configuration includes the CBCT option. The device is operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.
Identification of Predicate Device:	CEFLA S.C. will refer to the following predicate device: Proprietary Name: hyperion X5, NewTom GO, X-RADiUS COMPACT Classification Name: Computed tomography x-ray system, 21 CFR 892.1750 Product Code: OAS, MUH Applicant/Manufacturer: Cefla S.C. Via Selice Provinciale 23/c 40026 Imola (BO) - Italy 510 (k): K200688
Identification of Reference Device:	CEFLA S.C. will refer to the following reference device: Proprietary Name: hyperion X9 Pro Classification Name: Computed tomography x-ray system, 21 CFR 892.1750 Product Code: OAS, MUH Applicant/Manufacturer: CEFLA S.C. Via Selice Provinciale 23/c 40026 Imola (BO) - Italy 510 (k): K223794

Comparison of technological characteristics with the predicate and reference devices:

Characteristic	Proposed Device	Predicate Device	Reference Device
Device Name	**ProXIma X6**	**hyperion X5, NewTom GO, X-RADiUS COMPACT**	**hyperion X9 pro**
Manufacturer	**CEFLA S.C**	**CEFLA S.C.**	**CEFLA S.C.**
510(K) No.	**-**	**K200688**	**K223794**
Regulation Number	892.1750	892.1750	892.1750
Regulation Name	Computed tomography x-ray system	Computed tomography x-ray system	Computed tomography x-ray system
Regulatory Class	Class II	Class II	Class II
Classification Product Code	OAS (Classification Product Code) MUH (Subsequent Product code)	OAS (Classification Product Code) MUH (Subsequent Product code)	OAS (Classification Product Code) MUH (Subsequent Product code)
Indication for use	ProXIma X6 is an extra-oral X-ray equipment for digital panoramic, tomographic and cephalometric Xrays exams, indicated for the following: (I) **production of orthopanoramic images** of the maxillofacial area, diagnostic dental exams on teeth, dental arches and other structures of the oral cavity; (II) **Production of X-ray images** of the dental arches, parts of the cranium and of the carpus in support of cephalometric examination, where the configuration includes the CEPH arm; (III) **production of tomographic images** of the structures of the maxillofacial area and oral cavity for diagnostic dental exams on teeth, dental arches, the structures of the oral cavity,	The **hyperion X5** is a digital extra-oral X-ray system for panoramic, cephalometric and tomographic images, intended to: (I) **produce ortho-panoramic images** of the maxillofacial region and carry out diagnostic examination on teeth, dental arches and other structures in the oral cavity; (II) **produce X-ray images** of dental arches, cranium parts, and carpus in support of cephalometric examinations, if equipped with tele-X-ray arm (CEPH); (III) **produce tomographic images** of the oral and maxillofacial cavities structures, for the diagnostic examination of the dentition (teeth)	**hyperion X9 pro** is a digital panoramic, cephalometric and tomographic extra-oral X-ray system, intended to: (I) **produce orthopanoramic images** of the maxillofacial region and carry out diagnostic examination on teeth, dental arches and other structures in the oral cavity; (II) **produce radiographs** of jaws, parts of the skull and carpus for the purpose of cephalometric examination, when equipped with tele-radiographic arm (CEPH);

	where the configuration includes the CBCT option. The device is operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.	arches, structures of the oral cavity and of some skull bones. if equipped with CBCT option. The device is operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.	(III) the **production of tomographic images** of the head, including the ear, nose and throat (ENT), of the dento-maxillo-facial complex, teeth, mandible and maxilla, temporomandibular-articular joint (TMJ), other areas of the human skull and neck with sections of the cervical spine for use in diagnostic support, if equipped with the CBCT option. The device is operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.
Performance features			
Performance specification	Panoramic Computed tomography Cephalometric	Panoramic Computed tomography Cephalometric	Panoramic Computed tomography Cephalometric
Patient population	Adult Paediatric	Adult Paediatric	Adult Paediatric
Exposition selectable	2D: PAN, DENT, SIN, TMJ, PAN BITEWING, CEPH 3D: Computed Tomography (CBCT)	2D: PAN, DENT, SIN, TMJ, PAN BITEWING, CEPH 3D: Computed Tomography (CBCT)	2D: PAN, BTW (bitewing), DENT, SIN, TMJ, CEPH 3D: Computed Tomography (CBCT)
Technical & Functional features comparison: (A) X-Ray emission			
Tube voltage	60-90 kV	Panoramic (PAN) and Cephalometric (CEPH) exams: 60 - 85 kV - continuous emission	Panoramic (PAN) and Cephalometric (CEPH)

	Panoramic (PAN) and Cephalometric (CEPH): the voltage is continuous. CBCT: The voltage is pulsed with a predetermined duty cycle for tomographic acquisitions.	CBCT: 90 kV pulsed mode	exams: 60 - 85 kV - continuous emission CBCT: 90 kV pulsed mode
Tube current range	2D: 4 - 15 mA 2D/3D: 2 - 16 mA	4 – 15 mA	2 - 16 mA
Exposure Time range	2D mode: 1 s – 15 s continuous radiation 3D mode (only 2D/3D models): 1 s – 40 s pulsed mode	Panoramic: 1s–15s continuous radiation CBCT: 1s – 10 s pulsed mode	2D: 1s- 18s continuous emission CBCT: 1s -10.4 s pulsed emission
Shape of X-Ray Beam	PAN: Fan-shaped beam CEPH: Fan-shaped beam CBCT: cone beam	PAN: Fan-shaped beam CEPH: Fan-shaped beam CBCT: cone beam	PAN and CEPH: fan-shaped beam CBCT: cone beam
Focal Spot	For 2D models: 0.5, 0.6 mm For 2D/3D models: 0.6 mm	PAN, CEPH: 0.5, 0.6 mm CBCT: 0.6 mm	PAN, CEPH and CBCT: 0.5mm
Collimator	One standard primary collimator of fixed beam type, with a single field of irradiation of the x-ray beam for panoramic x-ray configurations. One primary collimator, adjustable in function of selected projection for 3D / 2D imaging configurations. One secondary collimator for CEPH.	One primary collimator, adjustable in function of selected projection. One secondary collimator for CEPH.	One primary collimator, adjustable in function of selected projection. One secondary collimator for CEPH. Correspondence between X-ray field and effective image reception area According to IEC 60601-2-63.
FOV	Max 15x11 Min: 5x4	Max 10x10 Min: 6x6	Max: 16x18 cm min: 4x4 cm
Technical & Functional features comparison: (B) SSD Detector & IMAGE acquisition			
Image Detector Technology	Panoramic (PAN) and Cephalometric (CEPH) exams: CMOS or IGZO TFT CBCT: Amorphous Silicon or IGZO TFT	Panoramic (PAN) and Cephalometric (CEPH) exams: CMOS detector CBCT: Amorphous Silicon	2D X-ray imaging:

		Only for devices equipped with the CEPH arm option, PAN and CEPH Image detectors are interchangeable.	PAN and CEPH Image detectors are interchangeable.	1) CMOS detector with scintillator Direct Deposition CSI; 2) Direct conversion CMOS detector. 3D Image X-ray sensor CBCT: Amorphous Silicon Flat Panel.
	Sensor module 2D	CMOS detector (PAN/CEPH) 1501(S) / 2301(S) CMOS detector (PAN/CEPH) 2304	CMOS detector (PAN/CEPH) C10500D-70 / C10502D-70	CMOS detector (PAN/CEPH) C10500D-70/ C10502D-70 CMOS detector (PAN/CEPH) 1501S GigE / 2301S GigE CMOS detector (PAN/CEPH) UFS-150-44 / UFS- 225-44
	Sensor module 2D / 3D	IGZO detector EXPD (CBCT) 1616P IGZO detector (CBCT) 1616Z	Amorphous Silicon (CBCT) 1616DXT	Amorphous Silicon Flat Panel (CBCT) 1616DXT
	Image detectors dimension	**PAN:**	**PAN:** CMOS detector C10500D-70 6 x 148 mm	**PAN:** CMOS detector C10500D- 70 6 x 148 mm

		CMOS detector1501(S) 6.7 x 152 mm CMOS detector 1536 6.2 x 149 mm **CEPH:** CMOS detector2301(S) 6.7 x 228 mm CMOS detector 2304 6.2 x 223 mm **CBCT:** IGZO detector EXPD 1616P 159.544x159.544mm IGZO detector 1616Z 161.3x161.3mm	**CEPH:** CMOS detector C10502D-70 6 x 223 mm **CBCT:** Amorphous Silicon 1616DXT 162.56x162.56mm	CMOS detector 1501S GigE 6.7 x 152 mm CMOS detector UFS-150-44 4,4 x 153,6 mm **CEPH:** CMOS detector C10502D- 70 6 x 223 mm CMOS detector 2301(S) 6.7 x 228 mm CMOS detector UFS-225-44 4,4 x 230,4 mm **CBCT:** Amorphous Silicon Flat Panel 1616DXT 162 x 162 mm

	Detector Pixel size	CMOS detector (PAN/CEPH) 1501(S) / 2301(S): 99 µm CMOS detector (PAN/CEPH) 1536 / 2304: 97 µm IGZO detector EXPD (CBCT) 1616P: 98 µm IGZO detector (CBCT) 1616Z: 105 µm	CMOS detector (PAN/CEPH) C10500D-70 / C10502D-70: 100 µm Amorphous Silicon (CBCT) 1616DXT: 127 µm	CMOS detector (PAN/CEPH) C10500D-70 / C10502D-70: 100 µm CMOS detector (PAN/CEPH) 1501S GigE / 2301S GigE: 99 µm CMOS detector (PAN/CEPH) UFS-150-44 / UFS- 225-44: 100 µm Amorphous Silicon Flat Panel (CBCT) 1616DXT: 127 µm
	CBCT Conversion Screen (scintillator)	CsI	CsI	CsI
	PAN (CEPH) Conversion Screen (scintillator)	CsI	CsI	CsI
	Modulation transfer function (MTF)	≥57% @ 1 lp/mm (1x1)	57% @ 1 lp/mm (1x1)	>48% @ 1 lp/mm (1x1 mode)
	Detective quantum efficiency (DQE)	**PAN:**	70% @ 0 lp/mm (1x1)	

		CMOS detector 1501(S): 70% @ 0 lp/mm (1x1) CMOS detector 1536: 70% @ 0 lp/mm (1x1) **CEPH:** CMOS detector 2301(S): 70% @ 0 lp/mm (1x1) CMOS detector 2304: 70% @ 0 lp/mm (1x1) **CBCT:** IGZO detector EXPD 1616P: 65% @ 0 lp/mm (1x1) IGZO detector 1616Z: 78% @ 0 lp/mm (1x1)		70% @ 0 lp/mm (1x1)

	Source to image detector distance (SID)	2D PAN: 500 mm 2D CEPH: 1610 mm 3D CBCT: 500 mm	PAN: 500 mm CEPH: 1610 mm CBCT: 500 mm	PAN: 550 mm ± 5 mm CEPH: 1554 mm ± 8 mm CBCT: 650 mm ± 5 mm
	Acquisition path	3 axis - CBCT scan: 210°	2 axis – CBCT scan: 210°	2 axis – CBCT scan: 210°
	Technical & Functional features comparison: (C) Laser & positioning			
	Number of laser pointer	5 (3 on the monoblock, 2 on the patient arm)	3	6 (adjustable)
	Laser optical class	Class 1 for IEC 60825-1	Class 1 for IEC 60825-1	Class 1 according to IEC 60825-1
	Number of point of cephalostat	2 (adjustable)	3 (adjustable)	3 (adjustable)
	Technical & Functional features comparison: (D) Control & Viewing Software			

Control SW	Firmware (two possible configurations: 1. software on a general-PC (Windows PC) which is external to the device (Workstation); 2. two computers, an on-board machine (Acquisition Board) and an external computer (Workstation).	Firmware + VKB (on PC or Tablet)	Firmware (on board) + VKB
Viewing & reconstruction software	Neowise	NNT / iRYS	NNT / iRYS
Software validation	IEC62304 + Guidance FDA on MD SW	IEC62304 + Guidance FDA on MD SW	IEC62304 + Guidance FDA on MD SW
Technical & Functional features comparison: (E) Mechanical configurations			
Wall installation Suspended	Yes	Yes	Yes
Floor version with column	Yes	Yes	Yes
Floor version with column and standard base	Yes	Yes	Yes

Non-clinical Performance Testing:

Electrical safety Test was conducted and performed in accordance with IEC 60601-1.
Electromagnetical Compatibility test was conducted and performed in compliance with IEC 60601-1-2.
Furthermore, the proposed device has been tested in compliance with the standards IEC 60601-2-63 and IEC 60825-1.
The software has been developed and validated according to IEC 62304.
Performance tests have been performed in comparison with predicate device to demonstrate that the image quality and the radiation safety of the proposed device can be considered equivalent.
Bench testing was conducted for all newly introduced detectors per FDA guidance document, Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices.
Bench testing conducted was performed in accordance with IEC 61223-3-7.
Cybersecurity requirements were addressed per FDA guidance document, Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions.

Clinical Testing:

The clinical evaluation was conducted for all claimed imaging modes, as summarized in the table below. The table also identifies the detectors available for each device configuration, taking into account the specific imaging modes performed. Supporting evidence has been provided to demonstrate that the detector used in the clinical evaluation is representative of the subject device configurations with respect to image quality.

ProXIma X6-2D	
Panoramic Exams (2D): • PAN ADULT • PAN CHILD • BTW - BITEWING • DENT (complete or partial views) • SIN (FRONT, L ,R) • TMJ (front lat both)	**Cephalometric Exams (2D):** • PAN ADULT • PAN CHILD • BTW - BITEWING • DENT (complete or partial views) • SIN (FRONT, L ,R) • TMJ (front lat both)
DETECTORS	
CMOS detector 1501(S) CMOS detector 1536 CMOS detector 2301(S) CMOS detector 2304	CMOS detector 2301(S) CMOS detector 2304

ProXIma X6-3D		
Panoramic Exams (2D): • PAN ADULT • PAN CHILD • BTW - BITEWING • DENT (complete or partial views) • SIN (FRONT, L ,R) • TMJ (front lat both)	**Cephalometric Exams (2D):** • PAN ADULT • PAN CHILD • BTW - BITEWING • DENT (complete or partial views) • SIN (FRONT, L ,R) • TMJ (front lat both)	**Tomographic CBCT Exams (3D):** • DENT 3D • SIN 3D • TMJ 3D
DETECTORS		
IGZO detector EXPD 1616P (panmode) IGZO detector 1616Z (panmode)	CMOS detector 2301(S) CMOS detector 2304	IGZO detector EXPD 1616P IGZO detector 1616Z

Conclusion:	CEFLA S.C. considers the ProXIma X6 (and all other different brand names) to be substantially equivalent to the predicate device. This conclusion is based on the similarities in intended use, principle of operation, functional design, and established medical use. Differences between the devices shown in the comparison section above are minor and do not have any negative effect on substantial equivalence.