January 20, 2022

CEFLA S.C.
℅ Mr. Lorenzo Bortolotti
Via Selice Provinciale 23/a
Imola, BO 40026
ITALY

Re: K214084
Trade/Device Name: hyperion X9 pro, NewTom GiANO HR, X-RADiUS TRiO PLUS
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS, MUH
Dated: December 20, 2021
Received: December 27, 2021

Dear Mr. Bortolotti:

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,

, for

Thalia T. Mills, Ph.D.
Director
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)*
K214084

Device Name
hyperion X9 pro, NewTom GiANO HR, X-RADiUS TRiO PLUS

Indications for Use *(Describe)*
hyperion X9 pro, NewTom GiANO HR, X-RADiUS TRiO PLUS is digital panoramic, cephalometric and tomographic extra-oral 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, if equipped with tele-radiographic arm (CEPH);
(III) the production of tomographic images of the head, including the ear, nose and throat (ENT), of the dento-maxillofacial 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.

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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510(k) SUMMARY AS REQUIRED BY 21 CFR 807.92

K214084

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
Contact Person: Lorenzo Bortolotti, Regulatory Affairs
Telephone Number: +39 0542 653441
Email Address: regulatory@cefla.it
Date prepared: December 15th, 2021

Device name: hyperion X9 pro, NewTom GiANO HR, X-RADiUS TRiO PLUS
Common Name: Extra oral source, Panoramic, Cephalometric, Computed tomography X-ray system
Device Classification Name: Computed Tomography X-ray System
Regulation Number: 21 CFR §892.1750
Device Class: Class II
Classification Product Code: OAS
Subsequent Product Code: MUH

Device Description: The Proposed device is a panoramic, cephalometric and tomographic radiological system developed and manufactured by CEFLA S.C. The proposed device is a change of the predicate device: hyperion X9 pro (K190496).
Like the predicate device the proposed device can be sold under three different proprietary product name and brands for commercial needs, without changing any of the basic safety, essential performances and functional features:

#	Device Name	Brand	Manufacturer
1	hyperion X9 pro	myray	CEFLA S.C.
2	NewTom GiANO HR	NewTom	CEFLA S.C.
3	X-RADiUS TRiO PLUS	Castellini	CEFLA S.C.

Wherever the Proposed device is mentioned, it is intended the device with its three different trade/ proprietary names: hyperion X9 pro, NewTom GiANO HR and X-RADiUS TRiO PLUS.

	Like the predicate device hyperion X9 pro (K190496) the proposed device is equipped with X-ray tube generator and X-ray sensors (solid state X-ray imaging detectors) for dental panoramic (PAN), cephalometric radiography (CEPH) and cone beam computed tomography (CBCT). The proposed device permits to acquire radiological images (panoramic images, cephalometric images and 3D volumes) at varying radiographic angles by rotating around the patient following different trajectories depending on the selected examination. The exposed area can be adapted to a specific region of interest to keep the radiation dose as low as possible for the patient. This is achieved by collimating the x-ray beam and the adjustment of starting and ending points of the x-ray source and sensor movement. Furthermore, the radiation dose can be adapted by various parameters such as examination types and exposure technique factors. Class I lasers pointers are utilized to define reference lines for the patient position. The patient, stabilized through adjustable patient supports, can sit or stand. Control panel allows user actions as: height adjustment, selection of examination, and exposure parameters and delivers information about the unit status. The obtained digital image data are processed to provide a reconstructed image. The images are transferred to a computer, in real time or later depending on the needs and choice of the operator. The software used to manage the images, essential for CBCT acquisitions, is NNT/iRYS, a radiological imaging software developed by CEFLA S.C.
Indication for Use:	The device 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, if equipped with tele-radiographic arm (CEPH); (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.
Identification of Predicate Device	The **predicate device** identified relating the substantial equivalence of the proposed device is: Device Names: hyperion X9 Pro, NewTom GiANO HR, X-RADiUS TRiO PLUS 510(k) Number: K190496 Device Classification Name: X-Ray, Tomography, Computed, Dental Applicant: CEFLA S.C. Via Selice Provinciale 23/A Imola, IT 40026 Regulation Number: 21 CFR §892.1750 Device Class: Class II Classification Product Code: OAS Subsequent Product Code: MUH

Substantial Equivalence

Both Proposed device and Predicate device hyperion X9 pro (K190496) permit the acquisition of panoramic images (PAN), cephalometric images (CEPH) and cone beam computed tomography images (CBCT).
The proposed device is a change of the Cefla's own legally marketed predicate device: hyperion X9 pro (K190496).
This device change makes available for the acquisition of 2D images (PAN, CEPH) alternative X-ray Direct conversion sensors in addition to the X-ray Scintillator sensors (detectors) already used in the predicate device hyperion X9 pro (K190496).

The following cross reference table shows similarity and diversity aspects between the proposed device and the Predicate device.

	Proposed Device	**Predicate Device (A)**	**Justification for Differences**
Device Name	**hyperion X9 pro, NewTom GiANO HR, X-RADiUS TRiO PLUS**	**hyperion X9 pro NewTom GiANO HR, X-RADiUS TRiO PLUS**	
Manufacturer	**CEFLA S.C.**	**CEFLA S.C.**	
510(K) No.	**K214084**	**K190496**	
Figure			The external appearances and materials between Proposed device and Predicate device are identical.
Classification and indication for use			
Regulation Number	21 CFR 892.1750	21 CFR 892.1750	No difference.
Regulatory Class	Class II	Class II	No difference.
Classification Product Code	OAS (Classification Product code) MUH (Subsequent Product code)	OAS (Classification Product code) MUH (Subsequent Product code)	No difference.

Classification Name:	Computed Tomography X-ray System	Computed Tomography X-ray System	No difference.
Indication for use	The device 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, if equipped with tele-radiographic arm (CEPH); (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.	The device 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, if equipped with tele-radiographic arm (CEPH); (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.	No difference.
Performance features			
Performance specification	Panoramic Computed tomography Cephalometric	Panoramic Computed tomography Cephalometric	No difference.
Patient population	Adult, Pediatric	Adult, Pediatric	No difference.

Exposition selectable	2D: PAN, BTW (bitewing), DENT, SIN, TMJ, CEPH 3D: Computed Tomography (CBCT)	2D: PAN, BTW (bitewing), DENT, SIN, TMJ, CEPH 3D: Computed Tomography (CBCT)	No difference.
Technical & Functional features comparison: Rated input			
Rated input	20A @ 115V~ 12A @ 240V~ 50/60 Hz	20A @ 115V~ 12A @ 240V~ 50/60 Hz	No difference.
Technical & Functional features comparison: X-Ray emission			
Tube voltage	Panoramic (PAN) and Cephalometric (CEPH) exams: 60 - 85 kV - continuous emission CBCT: 90 kV pulsed mode	Panoramic (PAN) and Cephalometric (CEPH) exams: 60 - 85 kV - continuous emission CBCT: 90 kV pulsed mode	No difference.
Tube current range	2 - 16 mA	2 - 16 mA	No difference.
Exposure Time range	2D: 1s- 18s continuous emission CBCT: 1s -10.4 s pulsed emission	2D: 1s - 18s continuous emission CBCT: 1s - 10.4 s pulsed emission	No difference.
Shape of X-Ray Beam	PAN and CEPH: fan-shaped beam CBCT: cone beam	PAN and CEPH: fan-shaped beam CBCT: cone beam	No significant difference.
Focal spot size According IEC 60336	PAN, CEPH and CBCT: 0.5mm	PAN, CEPH and CBCT: 0.5mm	No difference.
Anode Inclination	10°	10°	No difference.
Collimator	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.	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.	The beam limiter structure and functioning are identical between Proposed Device and Predicate Device. Only the beam limiter windows size has been changed on Proposed Device when 2D Direct Conversion X-ray sensors are installed. However the correspondence between X-ray field and effective image reception area is conforming the same recognized consensus standard IEC 60601-2-63 .
FOV (3D)	Max: 16x18 cm min: 4x4 cm	Max: 16x18 cm min: 4x4 cm	No difference.

Total filtration for scansions	2D > 2,5 mm Al @85kV 3D 6.5 mm Al @ 90 kV	2D > 2,5 mm Al @85kV 3D 6.5 mm Al @ 90 kV	No significant difference between Proposed Device and Predicate device on declared 2D equivalent filtration.
2D operating modes min and MAX Dose Area Product DAP (mGy*cm2), Typical Range	1) Sensors with scintillator: 11 mGy*cm2 (exam: CEPH Lat. Short reduced Quick, Small Patient Size) - 126 mGy*cm2 (exam PAN Ortho, Large Patient Size) 2) Direct conversion sensors: 7 mGy*cm2 (exam: CEPH Lat. Short reduced Quick, Small Patient Size) - 103 mGy*cm2 (exam: PAN Ortho Large Size Patient)	Sensor with scintillator: 13.01 mGy*cm2 (exam: CEPH Lat. Short reduced Quick, Small Patient Size) - 229,81 mGy*cm2 (exam: PAN Ortho, Large Patient Size)	The Proposed Device showed similar or lower measured DAP values than Predicate Device for the same selected exams.
Technical & Functional features comparison: SSD X-ray sensor & IMAGE Acquisition			
Image X-ray sensors Technology	2D X-ray imaging: 1) CMOS X-ray sensor with scintillator Direct Deposition CSI; 2) Direct conversion CMOS sensor. CBCT Image X-ray sensor: Amorphous Silicon Flat Panel.	2D X-ray imaging: CMOS X-ray sensor with scintillator Direct Deposition CSI. CBCT Image X-ray sensor: Amorphous Silicon Flat Panel.	The Proposed Device is available with the same 2D CMOS X-ray sensors with scintillator used on Predicate Device or with Direct Conversion 2D CMOS X-ray sensors. Both Proposed Device and Predicate Device use the same CBCT Flat Panel X-ray sensor.

Image X-ray sensors dimensions	2D X-ray imaging: 1) Sensors with scintillator PAN: 148 mm x 6 mm CEPH: 223 mm x 6 mm 2) Direct conversion sensors. PAN: 153,6 mm x 4,4 mm CEPH 230,4 mm x 4,4 mm 3D Image X-ray sensor: CBCT: 162 x 162 mm	2D X-ray imaging: Sensors with scintillator PAN: 148 mm x 6 mm CEPH: 223 mm x 6 mm 3D Image X-ray sensor: CBCT: 162 x 162 mm	The Direct conversion X-ray sensors available with Proposed Device are higher and tighter than the X-ray sensors with scintillator. The correspondence between X-ray field and effective image reception area is conforming the same recognized consensus standard IEC 60601-2-63 applied to both Proposed Device and Predicate Device thus it doesn't involve in different risks and safety considerations. The 3D X-ray sensor dimensions are identical between Proposed Device and Predicate Device because both devices use the same CBCT Flat Panel.
Image X-ray sensors Pixel size	2D X-ray imaging: 1) Sensors with scintillator PAN and CEPH: 100x100 µm 2) Direct conversion sensor PAN and CEPH: 100x100 µm 3D Image X-ray sensor: CBCT: 127x127 µm	2D X-ray imaging: Sensors with scintillator PAN and CEPH: 100x100 µm 3D Image X-ray sensor: CBCT: 127x127 µm	No difference between Proposed Device and Predicate Device. The 2D sensor pixel sizes are identical between Proposed Device and Predicate Device. The 3D X-ray sensor pixel sizes are identical between Proposed Device and Predicate device because both devices use the same CBCT Flat Panel.
Source to image X-ray sensor distance (SID)	PAN: 550 mm ± 5 mm CEPH: 1554 mm ± 8 mm CBCT: 650 mm ± 5 mm	PAN: 550 mm ± 5 mm CEPH: 1554 mm ± 8 mm CBCT: 650 mm ± 5 mm	No difference between Proposed Device and Predicate Device. The two devices mechanical structure is the same.
Technical & Functional features comparison: Laser & positioning			
Laser pointers optical class	Class 1 according IEC 60825-1:2014	Class 1 according IEC 60825-1:2014	No difference.
Number of fixing points of craniostat	6 (adjustable)	6 (adjustable)	No difference.
Number of fixing points of cephalostat	3 (adjustable)	3 (adjustable)	No difference.
Technical & Functional features comparison: Control & Viewing Software			

Control software	Firmware (on board)	Firmware (on board)	The firmware on board has been updated to manage also the 2D direct conversion X-ray sensors. The changes have been managed according to the same recognized consensus IEC 62304 and FDA Guidance on Medical Device Software.
Graphical User Interface (GUI)	VKB	VKB	No significant differences.
Viewing & Reconstruction software	NNT / iRYS	NNT / iRYS	The viewing software has been updated to manage also the images from 2D direct conversion X-ray sensors. The changes have been managed according to the same recognized consensus standard IEC 62304 and FDA Guidance on Medical Device Software.
Software validation	IEC 62304 + Guidance FDA on MD SW	IEC 62304 + Guidance FDA on MD SW	No difference.
Electrical Safety & Electromagnetic compatibility			
Electrical safety	Complies with IEC 60601-1: 2012	Complies with IEC 60601-1:2012	No difference.
Electromagnetic compatibility	Complies IEC 60601-1-2:2014	Complies IEC 60601-1-2:2014	No difference.

Non-clinical Performance Testing:

Testing to verify the performance requirements of the proposed device was conducted and included in this premarket notification. The results of the performance testing support substantial equivalence.

Tests included in this premarket notification verify the conformity of the proposed device with the requirements of:

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (including US National Differences, Canadian National Differences and Korean National Differences).
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC 60825-1: Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-3: Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.
- IEC 62366: Medical devices - Application of usability engineering to medical devices.
- IEC 62304: Medical device software - Software lifecycle processes.

	• IEC 60601-2-63: Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment. • IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability. • Verification activities for confirmation of the image quality of the proposed device has been performed. The results of the image quality review have demonstrated that the device is substantially equivalent to the predicate device.
Clinical Testing	Given the differences from the predicate device, no human clinical studies have been considered necessary to support substantial equivalence.
Conclusion	The information included in this premarket notification supports the substantial equivalence of the proposed device. The proposed device is a change of the Cefla's own legally marketed predicate device: hyperion X9 pro (K190496). The proposed device has identical intended use and fundamental principles of operation. The proposed device showed comparable basic safety and essential performances as the legally marketed predicate device. Differences between the devices shown in the comparison section above do not reasonably involves in negative effects on substantial equivalence.