CEFLA S.C.
℅ Lorenzo Bortolotti
Regulatory Affairs
Via Selice Provinciale 23/A
Imola, Bologna 40026
ITALY

April 9, 2020

Re: K200688
Trade/Device Name: hyperion X5, NewTom GO, X-RADiUS COMPACT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS, MUH
Dated: March 9, 2020
Received: March 16, 2020

Dear Lorenzo 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200688

Device Name
hyperion X5, NewTom GO and X-RADiUS COMPACT

Indications for Use *(Describe)*
hyperion X5 is an extraoral X-ray system for digital panoramic exams, tele-X-rays and tomographies, intended to:
1. produce orthopanoramic images of the maxillofacial region and carry out diagnostic examination on teeth, dental arches and other structures in the oral cavity:
2. produce X-ray images of dental arches, cranium parts, and carpus in support of cephalometric examinations, if equipped with tele-X-ray arm (CEPH);
3. produce tomographic images of the oral cavity and maxillofacial structures and carry out diagnostic examination on teeth, dental arches, structures of the oral cavity and some cranial bones, if equipped with 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)

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510(k) Summary

hyperion X5, NewTom GO and X-RADiUS COMPACT

This 510(k) Summary of Safety and Effectiveness information is prepared according to the requirements of 21 CFR Part 807.92.

1. General Information

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Date 510K summary prepared: March 9, 2020

2. Names

Trade/ Device name:	hyperion X5, NewTom GO, X-RADiUS COMPACT
Common or Usual Name:	Extra oral source, Panoramic, Cephalometric, Tomography X-ray system
Regulatory Name:	Computed tomography X-ray system
Regulation number:	21 CFR 892.1750
Regulation Class:	Class II
Product Codes:	OAS
Subsequent code:	MUH

3. Predicate Devices

Proposed device is substantially equivalent to the following legally marketed predicate devices:

Applicant	Device Name	510(k) Number	Product Code
CEFLA S.C.	hyperion X9 pro	K190496	OAS MUH

Furthermore, the devices indicated in the table below, already cleared by FDA, has been considered in this submission as reference device.

Applicant	Device Name	510(k) Number	Product Code
CEFLA S.C.	hyperion X5 3D version	K161900	OAS MUH
CEFLA S.C.	hyperion X5 2D version	K152162	MUH

4. Device Description

The proposed device is a panoramic (PAN, 2D), cephalometric (CEPH, 2D) and tomographic (CBCT, 3D) radiological system, that acquires radiological images by rotating around the patient. The rotating arm is attached to a support column capable of moving vertically through a motorized movement.

The system is equipped with X-ray tube generator and detectors (sensors) for dental panoramic (PAN), cephalometric radiography (CEPH) and cone beam computed tomography (CBCT).

The proposed device can be sold under three different product name and brands names for commercial needs, without changing any of the safety, electrical and functional features.
The variants are:

#	Device Name	Brand	manufacturer
1	hyperion X5	myray	CEFLA S.C.
2	NewTom GO	NewTom	CEFLA S.C.
3	X-RADiUS COMPACT	Castellini	CEFLA S.C.

Wherever the proposed device is mentioned, it is intended the device with its three different trade/ device names: hyperion X5, NewTom GO and X-RADiUS COMPACT.

5. Indications for Use

hyperion X5 is an extraoral X-ray system for digital panoramic exams, tele-X-rays and tomographies, intended to:

1. produce orthopanoramic images of the maxillofacial region and carry out diagnostic examination on teeth, dental arches and other structures in the oral cavity;
2. produce X-ray images of dental arches, cranium parts, and carpus in support of cephalometric examinations, if equipped with tele-X-ray arm (CEPH);
3. produce tomographic images of the oral cavity and maxillofacial structures and carry out diagnostic examination on teeth, dental arches, structures of the oral cavity and some cranial bones, if equipped with CBCT option.

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

6. Comparison of technological characteristics with the predicate and reference devices

The proposed device hyperion X5 (PAN, CEPH, CBCT) is a simplified version of the predicate device hyperion X9 pro (K190496), and also a further development of the reference devices hyperion X5 3D version (K161900) and hyperion X5 2D version (K152162).

Both proposed device and predicate device hyperion X9 pro (K190496), permit the acquisition of panoramic images (PAN), cephalometric images (CEPH) and CBCT images (3D).
Compared to hyperion X9 pro (K190496), the proposed device is not intended to create tomographic images of the full head; ear, nose and throat (ENT); other areas of the human skull and neck with sections of the cervical spine for use in diagnostic support.

For panoramic acquisitions the proposed device provides similar technological characteristic, operating principles and features of the predicate device hyperion X9 pro (K190496) and the reference devices hyperion X5 2D version (K152162) and hyperion X5 3D version (K161900).

The cephalometric acquisitions of hyperion X5 are performed through a CMOS detector, similarly to the predicate device hyperion X9 pro (K190496): the quality of the images acquired by the two devices are substantially equivalent as demonstrated through performance tests.

For CBCT image acquisition and 3D processing the proposed device provides the same operating principles and similar technology of hyperion X9 pro device (K190496) and hyperion X5 3D version (K161900).

Main Difference:
Indication for use: Compared to predicate device hyperion X9 pro (K190496), the proposed device is NOT intend to create tomographic images of the full head, the ear, nose and throat (ENT) and neck with sections of the cervical spine mainly due from the available FOVs and mechanical dimensions. Thus, proposed device is a simplified version of the predicate device.

The following cross reference table shows similarity and diversity aspects between the proposed device and the Predicate / Reference devices:

	Proposed Device	**Predicate Device**	**Reference Devices**	
Product Name	**hyperion X5, NewTom GO, X-RADiUS COMPACT**	**hyperion X9 pro**	**hyperion X5 3D version**	**hyperion X5 2D version**
Manufacturer	**CEFLA S.C.**	**CEFLA S.C.**	**CEFLA S.C.**	**CEFLA S.C.**
510(K) No.	**-**	**K190496**	**K161900**	**K152162**
Classification and indications for use				
Regulation Number	892.1750	892.1750	892.1750	872.2100
Regulation Name	Computed tomography x-ray system	Computed tomography x-ray system	Computed tomography x-ray system	Extraoral Source X-Ray System
Regulatory Class	Class II	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)	MUH

Indication for use	The **hyperion X5** is an extraoral X-ray system for digital panoramic exams, tele-X-rays and tomographies, 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 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 cavity and maxillofacial structures and carry out diagnostic examination on teeth, dental arches, structures of the oral cavity and some cranial bones, if equipped with CBCT option. The device is operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.	The **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); **(III) produce 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 **hyperion X5** device, **3D version** machine, is an image reproducer, for expert professionals, 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 tomographic images** of the oral cavity and maxillofacial structures and carry out diagnostic examination on teeth, dental arches, structures of the oral cavity and some cranial bones. The system performs tomographic exams with the acquisition of X-ray images through a rotating sequence and the reconstruction of a three-dimensional matrix of the examined volume, thus producing two- and three dimensional views of the volume itself. This technique is known as CBCT.	The **hyperion X5** device, **2D version** machine, is an extraoral X-ray system for digital panoramic X-Rays suitable for: **(I)produce orthopanoramic images** of the maxillofacial region, diagnostic examination of the dentition (teeth), arches and other structures of the oral cavity.

Performance features				
Performance specification	Panoramic Cephalometric Computed tomography	Panoramic Cephalometric Computed tomography	Panoramic Computed tomography	Panoramic
Patient population	Adult Paediatric	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, DENT, SIN, TMJ, PAN BITEWING 3D: Computed tomography (CBCT)	2D: PAN, DENT, SIN, TMJ 3D: N/A
DAP reduction between Panoramic Standard Child / Panoramic Standard Adult	0.7	0.7	0.7	0.7
Technical & Functional features comparison: (A) 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	PAN: 60 – 85 kV - continuous emission CBCT: 90kV pulsed mode	PAN: 60 – 85 kV - continuous emission
Tube current	4 – 15 mA.	2 – 16 mA	4 – 15 mA	4 – 15 mA
Exposure Time	Panoramic (PAN) and Cephalometric (CEPH): 1s - 15s continuous emission CBCT: 1 s – 10 s pulsed mode, effective emission time	Panoramic (PAN) and Cephalometric (CEPH): 1s - 18s continuous emission CBCT: 1s – 10.4 s pulsed emission, effective emission time	Panoramic: 1s - 15s continuous radiation CBCT: 6.4 s – 16.8 s pulsed mode, effective emission time	Panoramic: 1s - 15s continuous radiation
Shape of X-Ray Beam	PAN and CEPH: Fan-shaped beam CBCT: cone beam	PAN and CEPH: Fan-shaped beam CBCT: cone beam	PAN: Fan-shaped beam CBCT: cone beam	PAN: Fan-shaped beam
Focal Spot	PAN, CEPH: 0.5, 0.6 mm CBCT: 0.6 mm	PAN, CEPH, CBCT: 0.5 mm	PAN: 0.5 mm, 0.6 mm CBCT: 0.6 mm	PAN: 0.5 mm

Collimator	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.	One collimator, adjustable in function of selected projection.	One collimator, fixed.
FOV	Max 10x10 Min: 6x6	Max 16x18 Min: 8x6	Max: 10x10 Min: 6x6	NA
Technical & Functional features comparison: (B) SSD Detector & IMAGE acquisition				
Image Detector Technology	Panoramic (PAN) and Cephalometric (CEPH) exams: CMOS detector CBCT: Amorphous Silicon PAN and CEPH Image detectors are interchangeable.	Panoramic (PAN) and Cephalometric (CEPH) exams: CMOS detector CBCT: Amorphous Silicon PAN and CEPH Image detectors are interchangeable.	PAN: CMOS detector CBCT: Amorphous Silicon	PAN: CMOS linear detector
Image detectors dimension	PAN:6 x 148 mm CEPH: 6 x 223 mm CBCT: 162 x 162 mm	PAN:6 x 148 mm CEPH: 6 x 223 mm CBCT: 162 x 162 mm	PAN: 6 x 146 mm CBCT:146 x 146 mm	PAN: 6 x 151 mm
Detector Pixel size	PAN: 100, 127 μm^2 CEPH: 100 μm^2 CBCT: 127 μm^2	PAN: 100 μm^2 CEPH: 100 μm^2 CBCT: 127 μm^2	PAN: 127 μm^2 CBCT: 127 μm^2	PAN: 100 μm^2
PAN (CEPH) Conversion Screen (scintillator)	CsI	CsI	CsI	CsI
CBCT Conversion Screen (scintillator)	CsI	CsI	CsI	N/A
MTF	57% @ 1 lp/mm (1x1)	57% @ 1lp/mm (1x1)	58% @ 1lp/mm (1x1)	58% @ 1lp/mm
DQE	70% @ 0 lp/mm (1x1)	70% @ 0lp/mm (1x1)	70% @ 0lp/mm (1x1)	70% @0lp/mm
Source to image detector distance (SID)	PAN: 500 mm CEPH: 1610 mm CBCT: 500 mm	PAN: 550 mm CEPH: 1554 mm CBCT: 650 mm	PAN: 500 mm CBCT: 500 mm	PAN: 500 mm
Acquisition path	2 axis – CBCT scan: 210°	3 axis – CBCT scan: 360° and 210°	2 axis – 210°	2 axis - 210°
Technical & Functional features comparison: (C) Laser & positioning				
Number of laser pointer	3	4	3	3

Laser optical class	Class 1 for IEC 60825-1	Class 1 for IEC 60825-1	Class 1 for IEC 60825-1	Class 1 for IEC 60825-1
Number of point of cephalostat	3 (adjustable)	3 (adjustable)	3 (adjustable along X-axis)	2 (fixed)
Technical & Functional features comparison: (D) Control & Viewing Software				
Control SW	Firmware (on board)	Firmware (on board)	Firmware (on board)	Firmware + VKB (on PC)
Graphical User interface	VKB (on PC or Tablet)	VKB (on board or Tablet or PC)	VKB (on PC or Tablet)	
Viewing & reconstruction software	NNT / iRYS	NNT / iRYS	NNT / iRYS	NNT / iRYS (optional)
Software validation	IEC 62304 + Guidance FDA on MD SW	IEC 62304 + Guidance FDA on MD SW	IEC 62304 + Guidance FDA on MD SW	IEC 62304 + Guidance FDA on MD SW

According to the table above, the proposed device has similar technology and features as the predicate device hyperion X9 pro (K190496) and the reference devices hyperion X5 3D version (K161900) and hyperion X5 2D version (K152162), pointing out only few differences that have been addressed by dedicated performance tests demonstrating that the proposed device is able to produce images with comparable performances. In conclusion, the different features of proposed system will not affect its classification, working principle, intended use, indications for use and target population and will not rise up new safety and effectiveness questions making proposed system equivalent to predicate device hyperion X9 pro (K190496) and reference devices hyperion X5 3D version (K161900) and hyperion X5 2D version (K152162).

7. Performance Data

The following performance test were executed in support of the substantial equivalence:

1) Non-clinical performance data:

A. Safety and EMC test in compliance with:

- IEC 60601-1,
- IEC 60601-1-2,
- IEC 60601-1-3,
- IEC 60601-2-63,
- IEC 60601-1-6,
- IEC 62366-1,
- IEC 62304,
- IEC 60825-1.

Obtained results demonstrate compliance to the standards listed.

B. Comparison with QUART Technical Phantom (DIN 6868-5) between hyperion X5 and X5 3D version (K161900) for Standard Panoramic X-Rays and between hyperion X5 and hyperion X9 pro (K190496) for the Standard Lateral Ceph X-rays. In both cases, the tested performances are: Spatial resolution and Low contrast resolution. The results obtained demonstrated a substantial equivalence in spatial resolution and in low contrast resolution, both in the comparison of the hyperion X5 with hyperion X5 3D version, and in the comparison between hyperion X5 and hyperion X9 pro.

C. Geometrical comparison performance: The proposed device hyperion X5 (PAN and CEPH projection) was tested in comparison with the reference device hyperion X5 3D version (K161900) and the teleradiograph projections with the predicate device hyperion X9 pro (K190496) using the specific technical phantoms. In the both case, we consider the two devices to be comparable in terms of distortion performance.

D. CBCT geometrical performance: the proposed device was tested using a specific phantom. Obtained results demonstrated that all the measured parameters fall between the acceptance range the same of reference device hyperion X5 3D version (K161900). Hence, that the performances of the proposed device hyperion X5 in terms of noise and geometric distortion are validated.

Obtained results demonstrated the substantial equivalence in geometrical performances.

E. The evaluation image quality of the PAN, CEPH and CBCT of hyperion X5, hyperion X9 pro (K190496) and hyperion X5 3D version (K161900). The quality of the evaluation image is performed in two steps.
   The images obtained with hyperion X5 on anthropomorphic and technical phantom, both in the 2D and 3D case, are compared with the corresponding tests of the reference device hyperion X5 3D version and the predicate device hyperion X9 pro.
   The performance of the system is validated by performing QA analysis with a suitable cylindrical phantom, with a positive result. It therefore concludes that the verification and validation of images originating from hyperion X5 has a positive outcome.

2) Image quality comparison:

In addition to the above summarized bench tests, the following comparison of clinical images of ***Image quality comparison*** has been performed:

a) Comparative Clinical Evaluation of 2D Panoramic X-rays taken on different patients with hyperion X5 and hyperion X9 pro (K190496);
b) Comparative Clinical Evaluation of CBCT X-ray images taken on the different patient with hyperion X5, hyperion X9 pro (K190496) and hyperion X5 3D version (K161900);
c) Comparative Clinical Evaluation of 2D Panoramic ORTO X-rays taken on the Same Patient with hyperion X5, hyperion X9 pro (K190496);
d) Comparative Clinical Evaluation of Tele-radiography X-¬rays taken on different patients with hyperion X5 and hyperion X9 pro (K190496);
e) Identification of main marker points of a Quick latero-lateral tele radiography acquired with hyperion X5;
f) On-field Clinical Evaluation of hyperion X5 and end-users feedback report.

Obtained results are able to demonstrate the substantial equivalence in performance.

Furthermore, the following FDA Guidance documents have been applied:

- Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices – September 1st, 2016
- Guidance for the content of Premarket Submissions for Software Contained in Medical Devices May 11, 2005
- Content of premarket submissions for Management of Cybersecurity in Medical Devices October 2, 2014
- Pediatric Information for X-ray Imaging Device Premarket Notifications – January 28, 2017

8. Conclusions

In conclusion of the tests summarized above and based on classification, intended use, technological characteristics and performance data, the device proposed with the trade names hyperion X5, NewTom GO and X-RADiUS COMPACT can be found substantially equivalent to the predicated devices hyperion X9 pro (K190496) and reference devices hyperion X5 3D version (K161900), hyperion X5 2D version (K152162).