DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 24, 2015

Cefla S.c.
% Maurizio Pantaleoni
CEO
Isemed Srl
Via A. Bonetti 3/a
Imola, 40026 IT

Re: K152162
Trade/Device Name: Hyperion X5
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: MUH
Dated: July 21, 2015
Received: August 3, 2015

Dear Maurizio Pantaleoni:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152162

Device Name
HYPERION X5

Indications for Use *(Describe)*

HYPERION X5 is an extraoral X-ray system for digital panoramic X-rays suitable for production of orthopanoramic images of the maxillofacial region, diagnostic examination of the dentition (teeth), arches and other structures of the oral cavity.

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 of the HYPERION X5

This 510(k) Summary is being submitted as required by **21 CFR 807.92.**

1. General Information

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Summary Prepared Date: **July 21, 2015**

2. Names

Device Name: HYPERION X5
Common Name: Panoramic x-ray system
Product Code: MUH
Classification: II
Regulation Number: 872.1800 (Extraoral source x-ray system)

3. Predicate Devices

The HYPERION X5 is substantially equivalent to the following device:

Applicant	Device name	510(k) Number
CEFLA S.C.	HYPERION X9	K123381

4. Device Description

The HYPERION X5 is manufactured by Cefla S.C. but it can be sold under two different brands and commercial name Hyperion X5 and NewTom GO. The device can be set in three different installation configurations: Suspended version, Floor version with column and wall bracket and Floor version with column and standard base.

The Hyperion X5 apparatus consists of one rotating arm attached to the support column. The powered rotating arm is capable of rotating for about 210° and translating thereby allowing the x-ray emission system and image detector to be moved around the patient according to complex orbits that follow the morphological profile. The rotating arm is attached to a support column capable of moving vertically through a motorized movement in order to allow it to perform the panoramic exposition.

The system provides patient positioning means such as handles and bite point with chin rest. The correct patient positioning is guided by 3 LASER positioning lights. The x-ray generator provides up to 85 kV, 15 mA to the x-ray tube, and the scanning process is performed by an independent axes cinematic unit. The system is equipped with CMOS solid state x-ray image detector, with associated electronics. The solid state CMOS detector contain a CsI(Tl) scintillator able to capture the radiation emitted by the x-ray generator, converting it in fluorescence and then in electric charge, accumulated by each pixel according to the light intensity. The accumulated charge in each row is sequentially selected by vertical shift registers for row scan, transferred to the amplifier and converted in voltage signal and than converted in a 14bit digital signal that transfered to the PC, trough the Ethernet connection, allow to create a set of by dimensional images acquired during the movement of the rotating arm along the designed orbits. These set of images suitably interconnected, allow at the software to create the panoramic standard image in order to show the exam result, store and evaluate it.

The HYPERION X5 system has been developed according to the FDA Guidance “Solid State X-ray Imaging Devices – Premarket Notification 510(k) submissions” of August 6, 1999.

5. Indications for Use

HYPERION X5 is an extraoral X-ray system for digital panoramic X-rays suitable for production of orthopanoramic images of the maxillofacial region, diagnostic examination of the dentition (teeth), arches and other structures of the oral cavity.

Hyperion X5 allows the following projections:

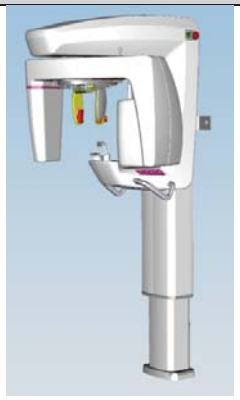
- Standard or pediatric panoramic views (PAN);
- Full or partial views of the dentition selected by the user (DENT);
- Frontal and lateral view of the maxillary sinuses (SIN);
- Lateral and posteroanterior view of the temporomandibular joints (TMJ) from several angles.

The HYPERION X5 shall not be used on patients (child) less than approximately 1045mm in height and less than 19Kg in weight. These height and weight measurements approximately correspond to that of an average 4 year old. Furthermore the device shall not be used with patients not vigilant and cooperative, since the patient must be able to understand and follow the operator's instructions for a correct positioning

The Hyperion X5 can perform panoramic views, both for adult and child, frontal and lateral view of the maxillary sinuses and Lateral and posteroanterior view of the temporomandibular joints exactly as the predicate device, there are no differences in indications for use of the two devices

The Indication for use for the HYPERION X5 are a subset of the indications for use of the predicate device only related to the 2D mode applications, since HYPERION X5 is a simplified version of the HYPERION X9.

6. Summary of comparison discussion

	Proposed Device	Predicate Devices
Device Name	**HYPERION X5** CEFLA S.C.	**HYPERION X9** CEFLA S.C. (K123381)
Figure		
Classification & Intended use		
Regulation Number	21CFR 872.1800	21CFR 892.1750
Regulation Name	Extraoral source x-ray system	Computed tomography x-ray system
Classification Product Code	MUH	OAS (Classification Product code) MUH (Subséquent Product code)
Regulatory Class	Class II	Class II
Indication for use statement	HYPERION X5 is an extraoral X-ray system for digital **panoramic X-rays suitable for production of orthopanoramic images of the maxillofacial region, diagnostic examination of the dentition (teeth), arches and other structures of the oral cavity.**	HYPERION X9 is a digital **panoramic**, cephalometric and tomographic extra-oral **X-ray system**, indicated for use in: (i) **producing panoramic X-ray images of the maxillofacial area, for diagnostic examination of dentition (teeth), jaws and oral structures; and** (ii) producing radiographs of jaws, parts of the skull and carpus for the purpose of cephalometric examination, when equipped with tele-radiographic arm (CEPH); (iii) producing tomographic images of the oral and maxillofacial structure, for diagnostic examination of dentition (teeth), jaws ,oral structures and some cranial bones if equipped with CBCT option.
Performances features comparison		
Performance Specification	Panoramic	Panoramic. Cephalometric and Computed tomography
Patient population	Adult & paediatric	Adult & paediatric
Exposition selectable	PAN, DENT, SIN, TMJ	PAN, DENT, SIN, TMJ (2D mode)
Patient type selectable	Male, female, child	Male, female, child
Patient size selectable	Large, medium, small for male an female patient Fixed for chid exposition	Large, medium, small for male an female patient Fixed for chid exposition

Dose reduction for child/adult (medium) exposition	0,7	0,6
Technical & Functional features comparison		
X-ray emission		
X-RAY GENERATOR VOLTAGE	60 – 85 kV, manually or automatically selectable, in steps of 1 kV	2D mode: 60 – 85 kV, automatic and manually selectable image acquisition in steps of 1 in the kV range. CBCT MODE: 60 – 90 kV, manually or automatically selectable, in steps of 1 kV
ANODIC CURRENT	4 – 15 mA selectable, in steps of 1 mA range.	1 – 10 mA, selectable, in steps of 1 mA range.
EXPOSURE TIME MAX (STANDARD PAN)	1s - 15s continuous radiation (depending on the 2D examination type selected)	1- 14s, continued exposure
SHAPE OF X-RAY BEAM	Fan-shaped x-ray beam	Fan-shaped x-ray beam and cone beam for tomography x-ray
TYPE OF X-RAY EMISSION	Continuous for PAN exams	Continuous for PAN and CEPH exams and pulsed for CBCT exams
EXPOSURE TIME (STANDARD CEPH)	N/A	4.6 s, continued exposure
EXPOSURE TIME (CBCT)	N/A	3.6 - 9 s, effective radiation time
STANDARDS	IEC60601-2-63	IEC60601-2-63
SSD Detector & IMAGE acquisition		
• PANORAMIC IMAGE DETECTOR	Digital CMOS linear detector	Digital CCD linear detector
• SCINTILLATOR MATERIAL	CSI	CSI
• MTF	58% @ 1lp/mm 8% @ 4 lp/mm	60% @ 1lp/mm (1x1) 10% @ 4lp/mm (1x1)
• DQE	70% @0lp/mm 18% @3lp/mm	80% @ 0lp/mm (1x1) 20% @3lp/mm (1x1)
• CEPHALOMETRIC • IMAGE DETECTOR	N/A	Digital CCD linear detector, Repluggable for panoramic exposure technique
• CBCT EXAMS • FLAT PANEL IMAGE DETECTOR	N/A	Amorphous Silicon flat panel X-ray detector (VARIAN manufacturer)
• IMAGE DETECTORS DIMENSION	PAN: 6 x 150 mm CEPH: N/A CBCT: N/A	PAN: 6 x 146 mm CEPH: 6 x 220 mm CBCT: 80x130, 130x130mm, 150x150 mm
• DETECTOR PIXEL SIZE:	PAN: 100 µm CEPH: N/A CBCT: N/A	PAN: 48 µm CEPH: 48 µm CBCT: 127 µm
• SOURCE TO IMAGE DETECTOR DISTANCE (SID)	PAN: 500 mm CEPH: N/A CBCT: N/A	PAN: 550mm CEPH:1500mm CBCT:660mm
• PANORAMIC IMAGE ACQUISITION PATH	2 axis - 210°	3 axis – 360°
• IMAGE TRANSFER TO PC	Direct – Giga Ethernet	Direct – Giga Ethernet for CBCT
Laser & positioning		
• NUMBER OF LASER POINTE	3 lasers pointers	3 lasers pointers
• LASER OPTICAL CLASS	Class 1 for IEC 60825-1: 2003	Class 1 for IEC 60825-1: 2003

Control & Viewing Software		
• CONTROL SW	Firmware + VKB (on PC)	Firmware
• VIEWING SOFTWARE	NNT / iRYS (optional)	NNT / iRYS (optional)
• SOFTWARE VALDATION	IEC62304 + Guidance FDA on MD SW	IEC62304 + Guidance FDA on MD SW

The HYPERION X5 is regulated under the 21 CFR 872.1800 as "Extraoral source x-ray system" with product code MUH, these regulation number and product code are different from the regulation number and classification product code of HYPERION X9 (K123381) that is regulated under 21 CFR892.1750 "Computed tomography x-ray system" with classification product code OAS , but the product code of the Hyperion X5 is equal to the subsequent product code of the predicate device (MUH), since the Hyperion X5 is a simplified version of the HYPERION X9 (K123381) able to perform only panoramic function instead of panoramic, cephalometric and computed tomography functions, performed by Hyperion X9.

Since HYPERION X5 is a simplified version of the HYPERION X9, it performs only panoramic X-ray in 2D mode and it did not produce other radiographic exposition as Cephalometric and Computed tomography. For this reason, the indications for use of the HYPERION X5 are a subset of the indications for use of the predicate device only related to the 2D mode applications.

Both the predicate device, are indicated to be used on adult and paediatric population, in both the machines, is possible select PAN, DENT, SIN, TMJ expositions selecting the kind of patients between Male, female and child, and in case of male and female (adults) is possible also select the size between large, medium and small. In both machines the child exposition is unique and no further subdivision of size are allowed.

About X-ray emission the X-ray tube head voltage for the Hyperion X5 is selectable in steps of 1 kV from 60 to 85 kV as in the predicate device when it works in 2D mode, while 5 the anodic current is selectable from 4 to 15mA, instead of the range of the anodic current selectable for the HYPERION X9 (K123381) that is from 1 to 10mA. The other features related to the X-ray emission, as the shape of the X-ray beam and the type of emission are respectively fan-shaped and continuous emission, both for Hyperion X5 that for predicate device. Since the X-ray emission has been validated in compliance with the same standard (IEC60601-2-63) both for Hyperion X5 that for Hyperion X9 (K123381) and that the effectiveness of the x-ray emission together with the SSD Detector and the image acquisition process has been compared in the specific comparative performance bench tests described in the section 7 "Performance data, these differences are not considered relevant for the substantial equivalence of the two devices

About SSD Detector & Image acquisition, the HYPERION X5 uses a linear CMOS detector made of CsI (Cesiume Iodide) material with a pixel dimension of 100 µm instead of the digital CCD sensor made of CsI used by the predicate device, but with a pixel dimension of 48 µm. The MTF value is very similar between the two sensor as the DQE. The path used to acquire the image, is different between the subject device and the predicate because the Hyperion X5 moves the rotating arm with a trajectory designed on 2 axis with a 210-degree rotation of the rotational arm, instead of the three axis with 360-degree rotation of the rotational arm, used by the Hyperion X9.

All these differences are not considered relevant for the substantial equivalence of the two devices because the images produced by the two sensors are considered comparable in term of technical features of the images (comparable resolution, distortion performances and with similar information in term of gray level, also in extreme exposition conditions) and also for the more significant clinical aspects required by a dentist

to this kind of device. These considerations are supported by the specific comparative performance bench tests described in the section 7 “Performance data”.

As the predicate devices HYPERION X9 (K123381), the HYPERION X5 uses luminous laser traces to guide patient positioning. These traces are projected by the identical class I laser beamers.

The viewing and control software used on the subject device is substantially equivalent to the one used for the predicate device, “Hyperion X9 (K123381)”, unless for the user interface used by the dentist to select the process parameters, that for the subject device has been developed with a specific Virtual Keyboard module that runs on a PC, and not directly installed into the firmware of the device.

The firmware and the software (VKB on PC) of the Hyperion X5, for the PAN, DENT, SIN, TMJ expositions, performs the same functions and algorithms of the predicate device, omitting all functions not related to the intended use as ie. CBCT exposition. Furthermore both the software has been validate in compliance to the IEC62304 and FDA Guidance on MD SW.

7. Performance Data

Since the “Guidance for the Submission of 510(k)’s for Solid State X-ray Imaging Devices” require to provide samples of test pattern images (SSXI and predicate) that show the ability of the device to provide images equivalent to those of a predicate device(s), CEFLA has performed some non clinical bench tests in order to compare the performances of the subject device with the Hyperion X9 (K123381). Furthermore

The non clinical performance tests executed are:

1. Comparison with QUART Technical Phantom (DIN 6868-5) on X9 and X5 Standard Panoramic X-rays. This test allow to demonstrate that both Hyperion X5 that the predicate device, together with their sensors and background software, are able to produce images with comparable level of resolution
2. Geometrical Comparison with Standard Technical CEFLA Phantom on 2D Dental Panoramic Projections. This test allow to demonstrate that both Hyperion X5 that the predicate device are able to produce images with comparable magnification of vertical and horizontal lines and orthogonality errors)
3. Comparison between Hyperion X5 and X9 Panoramic Under- and Over-Exposed X-ray. This test allow to evaluate the behaviour of the two devices, and in particular the behaviour of the two 2D sensors and of the two reconstruction software used in the subject device and in the predicate device, when a PANORAMIC exposition is performed in extreme exposition condition (under and over exposition).

Furthermore the Hyperion X5 is designed according to the FDA “Guidance for the Submission of 510(k)’s for Solid State X-ray Imaging Devices” and also designed, tested and found to be compliant with IEC 60601-1, 60601-1-2, 60601-1-3, 60601-1-6 and 62366, 60601-2-63 and 62304, exactly as its predicate devices

The non clinical performance tests allow to demonstrate that the images produced by the Hyperion X5 have similar resolution, similar geometrical performances (magnification of vertical and horizontal lines and orthogonality errors), similar ability to maintain information level, also in very extreme exposition conditions, and are also comparable in term of clinical outcome.

For these reasons the results of the non clinical performance together with the compliance to the same standards allow to demonstrate the substantial equivalence of the Hyperion X5 and the predicate device.

Conclusions

Do to all the above described reasons, we affirm that Hyperion X5 is substantially equivalent to the predicate device since it can be consider as safety and effectiveness as the predicate device.