DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 9, 2016

CEFLA S.C.
% Mr. Maurizio Pantaleoni
CEO
ISEMED srl
Via A. Altobelli Bonetti 3/A
Imola, BO 40026
ITALY

Re: K161900
Trade/Device Name: Hyperion X5
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS, MUH
Dated: October 21, 2016
Received: October 28, 2016

Dear Mr. 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, Ph.D.
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)*

K161900

Device Name
Hyperion X5

Indications for Use *(Describe)*

The Hyperion X5 device, 3D version machine, is an image reproducer suitable for expert professionals, which allows to obtain dental images in a simple and automatic way. The image is acquired by means of an X-ray detector and a constant potential X-ray source, powered by a high-voltage and high-frequency generator. The image is then transmitted to a computer in real time.

The Hyperion X5 device, 3D version machine, 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.

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 of Safety and Effectiveness information is prepared in accordance with the requirements of 21 CFR Part 807.92.

1. General Information

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Date 510K summary prepared: July 1, 2016

2. Names

Device Name: HYPERION X5
Common Name: Dental Computed Tomography X-ray System
Regulation Name: Computed Tomography X-ray System
Product Code: OAS/MUH
Classification: 21CFR 892.1750, Class II

3. Predicate Devices

The legally marketed device to which substantial equivalence is being claimed is as follows:

Applicant	Device name	Premarket Notification Number	Product code
CEFLA S.C.	HYPERION X9	K123381	OAS/ MUH
CEFLA S.C.	HYPERION X5	K152162	MUH

4. Device Description

The subject device Hyperion X5 is a dental radiographic imaging system, that consists of two image acquisition modes: panoramic and cone beam computed tomography (CBCT). Specifically designed for dental radiography of the teeth, jaws and oral structures, the subject device:

I. produces orthopanoramic images of the maxillofacial region and carry out diagnostic examination on teeth, dental arches and other structures in the oral cavity;

II. produces 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.

Hyperion X5 has been developed according to FDA-Guidance "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices".

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

#	Product Name	Brand	Manufacturer	REF – TYPE
1	***Hyperion X5***	Myray	Cefla s.c.	**708H**
2	***NewTom GO***	NewTom	Cefla s.c.	**708K**
3	***X-Radius Compact***	Castellini	Cefla s.c.	**708N**

5. Indications for Use

The Hyperion X5 device, 3D version machine, is an image reproducer suitable for expert professionals, which allows to obtain dental images in a simple and automatic way. The image is acquired by means of an X-ray detector and a constant potential X-ray source, powered by a high-voltage and high-frequency generator. The image is then transmitted to a computer in real time.

The Hyperion X5 device, 3D version machine, 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.

6. Comparison of technological characteristics with the predicate device

The subject device Hyperion X5 allows 2D as well as 3D images representing a further development of the cleared Hyperion X5 (K152162) which allows 2D images only.
For panoramicx-ray exposures (also referred to as "2D mode"), the subject device provides similar technological characteristic, operating principles, components and programs of the previous version Hyperion X5 (K152162). For CBCT image acquisition and 3D processing (also referred to as "3D

mode"), the subject device provides the same operating principles and similar technology of Hyperion X9 Computed Tomography X-ray System (K123381). In particular:

Characteristics	**Subject device**	**HYPERION X5** K152162	**HYPERION X9** K123381
Indication for use statement	The Hyperion X5 device, 3D version machine, 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	HYPERION X5 is an extraoral X-ray system for digital panoramic X-rays suitable for : (i) **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 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. (iii) producing radiographs of jaws, parts of the skull and carpus for the purpose of cephalometric examination, when equipped with tele-radiographic arm (CEPH);
Performance features			
Performance Specification	• Panoramic • Computed tomography	• Panoramic	• Panoramic • Computed tomography • Cephalometric
Patient population	Adult Paediatric	Adult Paediatric	Adult Paediatric
Exposition selectable	2D : PAN, DENT, SIN, TMJ, PAN BITEWING 3D: Computed tomography (CBCT)	2D: PAN, DENT, SIN, TMJ	2D: PAN DENT, , SIN, TMJ,PAN BITEWING, CEPHALOMETRIC 3D: Computed tomography (CBCT)
Patient type selectable	Male Female Child	Male Female Child	Male Female Child
Patient size selectable	Male: Large, medium, small Female: Large, medium, small Child: Fixed	Male: Large, medium, small Female: Large, medium, small Child: Fixed	Male: Large, medium, small Female: Large, medium, small Child: Fixed

Dose reduction for child/adult male-standard exposition	0.7	0.7	0.6
Technical & Functional features comparison: (A) X-ray emission			
TUBE VOLTAGE	• Panoramic: 60 – 85 kV, - continuous emission • CBCT: 60 - 90kV pulsed	Panoramic: 60 – 85 kV, - continuous emission .	• Panoramic: 60 – 85 kV, - continuous emission . • CBCT: 60 – 90 kV pulsed
TUBE CURRENT	4 – 15 mA	4 – 15 mA	1 – 10 mA
EXPOSURE TIME	• Panoramic: 1s - 15s continuous radiation • CBCT: 1,6 – 5,6 effective radiation time,	Panoramic: 1s - 15s continuous radiation	• Panoramic. 1s - 14s continuous exposure CBCT: 3.6 s- 9 s effective radiation time
SHAPE OF X-RAY BEAM	• Panoramic: Fan-shaped beam • CBCT: cone beam	Panoramic: Fan-shaped beam	• Panoramic: Fan-shaped beam • CBCT: cone beam
FOCAL SPOT	• Panoramic: 0.5 mm • CBCT: 0.6 mm	Panoramic: 0.5 mm	• Panoramic: 0.5 mm • CBCT: 0.5 mm
COLLIMATOR	One collimator, adjustable in function of selected projection.	One collimator, fixed.	One primary collimator, adjustable in function of selected projection for CBCT (One secondary collimator for CEPH)
FOV	Max: 10x10 Child: 8x7	NA	Max 11x13 Child: 8x8: full dentition / 8x5: whole dental arch
Technical & Functional features comparison: (B) SSD Detector & IMAGE acquisition			
IMAGE DETECTOR TECHNOLOGY	• Panoramic: TFT detector • CBCT: TFT detector	Panoramic: CMOS detector	• Panoramic: CCD detector • CBCT: TFT detector
SCINTILLATOR MATERIAL	Direct deposition CsI	Direct deposition CsI	Direct deposition CsI
IMAGE DETECTORS DIMENSION	• Panoramic: 6 x 146 mm • CBCT: 146 x 146 mm	Panoramic: 6 x 151 mm	• Panoramic: 6 x 146 mm • CBCT: 130x130 mm
PIXEL SIZE	• 127 μm^2	Panoramic: 100 μm^2	• Panoramic: 96 μm^2 (2x2 binning mode) • CBCT: 127 μm^2
MTF	58% @ 1lp/mm (1x1)	58% @ 1lp/mm	60% @ 1lp/mm (1x1)
DQE	70% @ 0lp/mm (1x1)	70% @0lp/mm	80% @ 0lp/mm (1x1)
SOURCE TO IMAGE DETECTOR DISTANCE (SID)	• Panoramic: 500 mm • CBCT: 500 mm	Panoramic: 500 mm	• Panoramic: 550mm: • CBCT: 660 mm
ACQUISITION PATH	2 axis – 210°	2 axis - 210°	3 axis – 360°
IMAGE TRANSFER TO PC	Direct Giga ethernet	Direct Giga Ethernet	Direct-Giga Ethernet

Technical & Functional features comparison: (C) Laser & positioning			
NUMBER OF LASER POINTER	3	3	4
LASER OPTICAL CLASS	Class 1 for IEC 60825-1: 2003	Class 1 for IEC 60825-1: 2003	Class 1 for IEC 60825-1: 2003
NUMBER OF POINT OF CEPHALOSTAT	3 (adjustable along X-axis)	2 (fixed)	3 (fixed)
Technical & Functional features comparison: (D) Control & Viewing Software			
CONTROL SW	Firmware + VKB (on PC or Tablet)	Firmware + VKB (on PC)	Firmware
VIEWING & RECONSTRUCTION SOFTWARE	NNT / iRYS	NNT / iRYS (optional)	NNT / iRYS

According to table above, the subject device has similar technology and features than the predicate devices K123381 and K152162, pointing out only few differences that have been addressed by dedicated performance tests demonstrating that the subject device is able to produce images with comparable performances.

7. Performance Data

The following tests were performed for determination of substantial equivalence:

1) Non clinical tests performed on the subject device:
   A. Safety and EMC test in compliance with:
      - IEC 60601-1
      - IEC 60601-1-2,
      - IEC 60601-1-3,
      - IEC 60601-1-6
      - IEC 62366,
      - IEC 60601-2-63,
      - IEC 60825-1
      - IEC62304 (software)

      Obtained results demonstrate compliance to the standards listed.
   B. Images resolution (panoramic X-rays): The subject device (in 2D mode) was tested in comparison with the predicate K152162 using a specific QUART phantom. Obtained results demonstrated substantial equivalence in images resolution.
   C. Geometrical performance: The subject device (in 2D mode) was tested in comparison with the predicate K152162 using a specific geometric phantom. Obtained results demonstrated substantial equivalence in geometrical performance.
   D. Performance in extreme exposition conditions (under and over exposition): The subject device (in 2D mode) was tested in comparison with the predicate K152162 using an anthropomorphic phantom. Obtained results demonstrated substantial equivalence in performance in extreme conditions (under/over exposition).
   E. 3D Performance evaluation of the subject device in comparison with Hyperion X9 (K123381) has been developed, in order to asses 3D MTF and 3D NPS parameters,

comparing them with the same parameters of the predicate device Hyperion X9 (K123381). A number of axial images extracted by the volumetric reconstructions of phantom Catphan® 500, for both devices was acquired with different scan modalities in order to have broader information. The two devices give substantially equivalent results in terms of spatial resolution and noise power spectrum. This assures that the diagnostic images extracted from volumes acquired with subject device hyperion X5 are of good quality and effective in comparison to the predicate device.

2) Clinical tests performed on the subject device:
Images resolution and quality during in CBCT acquisition (3D configuration) - The subject device was tested in comparison with the predicate K123381 performing :
   - a quantitative evaluation by using a specific phantom as clinical case and measuring the resolution and noise.
   - a qualitative evaluation of images obtained with the two devices focusing on relevant clinical conditions: pediatric patient, Edentulous, third molar, Upper arch endodontics.

Clinical images were provided for the 2d mode of operation; these images were not necessary to establish substantial equivalence based on the modifications to the device (note digital image detector that is equivalent to the predicate image plate) but they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended."

8. Conclusions

In light of evidence summarized above and based on classification, intended use, technological characteristics, and performance data, the subject device may be found substantial equivalent to the predicate devices K152162 and K123381.