510(k) Summary
for the
Cefla, s.c. - Cefla Dental Group
Cefla MyRay Hyperion

K101661

SEP 16 2010

1. Sponsor

Cefla, s.c. - Cefla Dental Group
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Date Prepared: June 11, 2010

2. Device Name

Proprietary Name:	MyRay Hyperion
Common/Usual Name:	Dental Panoramic X-ray system
Classification Name:	System, x-ray, extraoral, source, digital

3. Predicate Devices

- Instrumentarium Dental Inc., Orthopantomograph OP200D (K043612)
- Sirona Dental System GmbH, Orthophos XG DS (K033073)
- Gendex, Orthoralix 9200 DDE (K032355)

4. Intended Use

The Cefla MyRay Hyperion is intended for use in producing panoramic-ray images of the maxillofacial region. It is used for the examination of teeth, the jaw, and oral structures.

5. Device Description

The MyRay Hyperion is a panoramic dental X-ray system which consists of a telescopic column, an overhead frame with a horizontal arm where an X-ray source and collimator and an X-ray image detector are mounted, and a console with a keyboard and display. The device includes a patient positioning system that consists of two handles which the patient grasps during exposures, a bite block, a frame for holding the head in the proper position and alignment with laser guide lights. The x-ray source and collimator generate a fan shaped x-ray beam which is projected through the patient's skull by the rotation of the

imaging unit. The x-ray image detector allows reconstruction of the diagnostic image, storage of the image in the buffer memory, and transfer of the image to an external PC (not provided by Cefla). A detailed description of the components is provided below.

Telescopic Column

The telescopic column supports the patient arm at which the patient stands during X-ray exposures. It also includes the patient handles which the patient holds during imaging and a plate which contains the mid-sagittal laser beam, the bite block and chin rest. The telescopic column allows adjustment of the patient arm to the patient's height.

Overhead Assembly

The overhead assembly supports the main horizontal and rotating arm. The rotating arm holds the x-ray generator and the collimator in a fixed position opposite to the x-ray image detector.

Console

The console allows the user to select the projection mode and the exposure factors, view the machine status information, control the height of the telescopic column, adjust the reset of the Y-axis, and turn on the laser guide lights. A system emergency stop button is included on the console so the user can immediately stop the procedure.

Control Panel

The control panel serves as the user interface with the electronic control system. The layout of the controls has been designed to split the panel into 2 sections. The "Procedure programming" area is found on the left side from which the user selects the type of procedure to be performed and technical settings. The "Assisted positioning" area is found on the right side of the panel which contains the controls to move the unit to position the patient. In addition, a port for an SD card (Secure Digital Memory Card) is provided at the bottom of the control panel. If this card is inserted, the images can be saved without having to connect the unit to a computer.

Control System

The electronic components which control the system operation consist of the following:

- Main unit- providing real-time system control as well as motor drive;
- Power unit- connecting to the mains power supply and providing the 400 VDC bus for the system;
- Converter unit- controlling the power to the x-ray generator;

- Sensor unit- controlling the x-ray image detector

6. Technological Characteristics and Substantial Equivalence

The Cefla MyRay Hyperion dental x-ray system is similar in design and materials to the Instrumentarium OP200D, subject of K043612, the Sirona Orthophos XG DS, subject of K033073, and the Gendex Orthoralix 9200 DDE subject of K032355. The similarities in intended use, operational characteristics, and functional technological characteristics between the MyRay Hyperion, OP 200D, and Orthophos XG DS dental x-ray systems lead to a conclusion of substantial equivalence between the proposed and predicate devices. A comparison between the features of the proposed device and those of the predicate devices is shown in Table 5-1 below:

Table 5-1. Comparison Table for Determination of Substantial Equivalence

Comparison Chart	Hyperion	Instrumentarium OP 200 D	Sirona Orthophos XG 5	Gendex Orthoralix 9200
Maximum total weight	145 kg	175 kg	183 kg	115-212 kg
Nominal voltage	230/115 VAC	230/115 VAC	230/115 VAC	250-115 VAC
Nominal frequency	60 Hz	60 Hz	60 Hz	60 Hz
X-ray source: geometry and type	Fan beam, High Frequency Constant Potential	Fan beam, High Frequency Constant Potential	Fan beam, High Frequency Constant Potential	Fan beam, High Frequency Constant Potential
X-ray source: focal spot	0.5mm	0.5mm	0.5mm	0.5 mm
X-ray source: max. energy	85 kVp	85 kVp	90 kVp	84 kVp
Exposure Time (std. panoramic)	9.3 s	17.6 s	14.2 s	12 s
Patient position	Lateral	Frontal	Frontal	Frontal
Detector: type	CCD	CCD	CCD	CCD
CCD pixel size	48 microns	48 microns	27 microns	48 microns
Detector area	147 x 6 mm	147 x 6 mm	N.A.	147 x 6 mm
Detector: gray scale	12 bit	12 bit	16 bit	12 bit
Image pixel size	96 x 96 microns	96 x 96 microns	N.A.	96 x 96 microns
Computer interface	LAN	Proprietary (PCI slot)	LAN	LAN
Patient positioning	3 laser lines	3 laser lines	2 laser lines	3 laser lines

NA=Not available, LAN=Local area network, PCI=Personal Computer Instrumentation

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Cefla Dental Group
% Ms. Mary McNamara-Cullinane
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Medical Device Consultants, Inc.
49 Plain Street
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SEP 16 2010

Re: K101661
Trade/Device Name: Cefla MyRay Hyperion
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: June 11, 2010
Received: June 14, 2010

Dear Ms. McNamara-Cullinane:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101661

Device Name: Cefla MyRay Hyperion

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Indications for Use:

The Cefla MyRay Hyperion is indicated for use in producing panoramic X-ray images of the maxillofacial region. It is used for the examination of teeth, the jaw, and oral structures.

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101661