Special 510(k) Summary
for
WDS X-POD and ZEN-X Digital X-Ray Sensors

1. SPONSOR

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2. DEVICE NAME

Proprietary Name:	WDS XPOD and ZEN-X
Common/Usual Name:	Intraoral X-ray sensor system
Classification Name:	Extraoral source x-ray system

3. PREDICATE DEVICE

WDS Digital X-Ray Sensors, Cefla, s.c. - Cefla Dental Group, K061114

4. INTENDED USE

The WDS X-POD and ZEN-X Digital X-Ray Sensors are intended to capture intraoral digital images when exposed to X-Rays. The process is automatic and transmits the digital image to a personal computer by wireless Bluetooth connection or by USB link. Additional legally marketed components such as conventional X-ray tubes and image capture software that are currently available commercially can be used with the WDS X-POD and ZEN-X Digital X-Ray Sensors.

5. DEVICE DESCRIPTIONS

The X-POD is comprised of the X-POD X-Ray sensitive digital sensor, with cable and connector, to be connected to a hand-held unit. X-POD X-ray Digital Sensor is a CMOS Sensor that receives the X-Ray image and converts it into an electronic format.

The X-POD hand-held unit receives the X-ray images from the sensor and stores them on an secure digital card. It includes a color display with touch-screen capability. The

display allows the user to check if the X-ray was correctly positioned on the image. It also includes an electronic board which allows the X-POD sensor to communicate with the PC through USB® and Bluetooth® links, and controls the display including the on-board circuits for charge control and monitoring the rechargeable battery. The X-POD handheld unit also includes an SD card to store the images.

A Wall mount Battery Charger is used for recharge of the internal battery, or to operate the hand-held unit when the battery level is under a minimum value. The battery charger provides 9VDC, 1.5A. The rechargeable battery pack supplies the electricity to the electronic board and the sensor. The battery compartment is enclosed by a screw-mounted panel and can only be replaced by qualified technicians (service).

The battery charger is used for fast recharge of the internal battery, or to operate the hand-held unit when the battery level is under a minimum value. The battery charger provides 9VDC, 1.5A. The battery charger is shown in Figure 3.

ZEN-X Digital X-Ray Sensor

The ZEN-X Sensor consists of the following components which are described in detail below:

- ZEN-X Intraoral Sensor
- ZEN-X interface
- CD-ROM with software, driver, and manuals

The ZEN-X intraoral sensor receives the X-ray image and converts it to an electronic format. The data from the X-ray image is transmitted from the sensor to the PC through the interface. The image data sent by the X-ray sensor is converted by the interface circuit into standard logic levels for the electronic circuit board to process the image data. The USB interface controls the flow of data and commands between the ZEN-X Interface and the computer. The ZEN-X Interface controls the timing and functions of the image data conversion and transmission.

6. Technical Characteristics and Substantial Equivalence

The overall design of the X-POD and ZEN-X Sensors are identical to the design of the parent WDS Sensor. The design modifications made to produce the X-POD and ZEN-X were implemented to improve the functional performance by allowing more images and ease of use of the digital X-ray sensor. The modifications are limited to changing the sensor from a CCD (charge coupled device) Sensor to a Complementary Metal Oxide Semiconductor (CMOS) sensor. The WDS X-POD and ZEN-X sensors when

exposed to radiation capture the image in the form of a charge pattern on its surface. The resulting electronic output signals are digitized by a processor and sent to a computer screen for image presentation

The appropriate design verification and design validation activities were conducted to address the potential risks identified in the Risk Analysis. These activities (discussed in Section 10.2) included electrical safety testing and electromagnetic compatibility testing to ensure that all design requirements were fulfilled. The results confirm that the modified X-POD and ZEN-X are safe and effective for capturing of digital X-ray images.

Based on the comparison of intended use and technical features, and considering the results of the design control activities, Cefla, s.c. - Cefla Dental Group believes that the X-POD and ZEN-X is substantially equivalent to the parent device, the WDS Sensor (K061114). The proposed and predicate devices have the same general intended use and principles of operation. The overall design of the proposed and predicate devices is similar. The differences between these devices are limited to design modifications implemented to improve the convenience and functional performance of the proposed devices. These design modifications are minor and raise no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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OCT 2 1 2010

Re: K100960
Trade/Device Name: WDS X-POD and ZEN-X Sensors
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: September 3, 2010
Received: September 8, 2010

Dear Dr. Notle:

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,

David G. Brown, Ph.D.
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): K100960

Device Name: WDS X-POD and ZEN-X Sensors

Indications for Use:

The WDS X-POD and ZEN-X Sensors are intended to capture intraoral digital images when exposed to X-Rays. The process is automatic and continues transmitting the digital image to a personal computer by wireless Bluetooth connection or by USB link. Additional legally marketed components such as conventional X-ray tubes and image capture software that are currently available commercially can be used with the WDS X-POD and ZEN-X Digital X-Ray Sensors.

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

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

510K K100960