K061114

510(K) SUMMARY

JUN - 6 2006

This summary of Safety and Effectiveness is in accordance with the requirements of:

- Device Description:

WDS is a wireless digital X-ray sensor for intraoral radiography.

- Intended Use:

The wireless digital X-ray sensor is intended to capture an intraoral digital X-ray image when exposed to X-Rays for diagnostic purposes. The process is automatic; it continues by transmitting the digital image to a Personal Computer via a wireless Bluetooth connection. It requires additional components such as conventional X-ray tube and image capture software, currently available commercially

- Summary of Substantial Equivalence Comparison:

K031448, RSV, VISIODENT

K050693 ACCENT, AIR TECHNIQUES, INC

K990002 QUICKRAY DSX730, JULIE ALLIANCE

The proposed and predicated devices use similar components and are similar in design, technical characteristics and mode of operation. All the systems include a scintillator coupled to a digital image sensor, electronic circuits to analyze the digital image and transmit the digital image to a personal computer for viewing and further management of the file. The proposed and the predicated devices are substantially equivalent;

- ACCENT is a wireless sensor very similar to WDS, the existing minor differences regarding use ergonomics only.

- QuickRay DSX730 is connected to the personal computer through a USB connector, and powered off the same connection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN - 6 2006

CEFLA s.c.r.l.
c/o Mr. Claude D. Berthoin
President
Video Dental Concepts, Inc.
110 E. Granada Blvd., Suite 207
ORMOND BEACH FL 32176

Re: K061114
Trade/Device Name: WDS
Regulation Number: 21 CFR §872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: April 20, 2006
Received: April 21, 2006

Dear Mr. Berthoin:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE

Applicant: CEFLA s.c.r.l.

510(k) Number (if known): K061114

Device Name: WDS

Indication For Use: the wireless digital RX sensor is intended to capture an intraoral digital RX image, when exposed to X-Rays, for diagnostic purposes.
The process is automatic and continues transmitting to a Personal Computer the digital image by wireless Bluetooth connection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE).

prescription Use ✓

David R. Hegarty

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061114