K053172

JUN - 9 2006

APPENDIX 7 : 510(K) SUMMARY

Premarket Notification for UNIVERSAL-X Dental imaging sensor

1 Submitter

OWANDY
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2 Device name

Proprietary name: UNIVERSAL-X
Classification name : Extra oral source X-Ray System accessory

3 Predicate devices

RVG TROPHY
RSV VISIODENT

4 Device description

The UNIVERSAL-X system consists of the following components : the sensor and its cable, a data box, and a PC with sensor adapter. The sensor body is made hermitically sealed shell which encapsulates a black and white CCD. The sensor attaches the processing unit via a 3 meters cable. The outer dimensions are approximately 42.77 X 28.40 mm with rounded edges.
The datas/USB box relays the data to the computer for display. The data box is a 44.5 mm X 161.2 X 154 mm box with an USB cable connection.
The sensor, when exposed to radiation, captures image in the form of a charge pattern on its surface (CCD). The resulting electronic signals are digitised and sent to a computer for image presentation.

5 Intended use

The UNIVERSAL-X digital system is used to provide instant digital images of human oral tissue and teeth without the use of a conventional x-ray film. It is used for diagnosis purpose, by dental practitioners.
This is achieved by using the conventional x-ray tube, and placing an electronic sensor in the patients mouth instead of conventional film.
The sensor , upon radiation exposure, automatically captures the images into a computer.
The computer , which is not provided by OWANDY, controls all aspects of image acquisition and image display, storage and printing.
Additional software (after, and not part of, image capture software) is available on the market. They allow for enhancements such as zoom, contrasts controls, image inversion, and pseudo color renditions.
The main advantages of this digital imaging system are:

- - high definition ensuring high-value diagnostics
- - interface allowing image processing in the PC

In no case, it has to be used directly by the patient. So, it is used exclusively in a healthcare specific environment.

6 Substantial equivalence and technological characteristics

The UNIVERSAL-X is substantially equivalent to several other digital dental imaging systems currently legally marketed in United States. The equivalent system examined are the RVG TROPHY (K950532) and the RSV VISIODENT (K031448).
All these products are intended to be used with a Dental X-ray source, a Dental Image Management Application Software and standard computer hardware for the capture, evaluation and storage of high quality digital dental X-ray mages using existing X-ray equipment.
The system and its predicates all consists of an X-ray sensitive solid state imaging array (CCD) installed in the Dental X-ray system in place of the traditional photographic film, connected via cable to digitising and control electronics which in turn interface to a computer via a standard interface. The proposed and predicate devices are intended for patients receiving routine dental radiography, in a clinical environment by dental professionals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN - 9 2006

Owandy SAS
% Mr. Olivier Maurier, CEO
Owandy Inc., Natexis Pramex North America Corp.
1251 Avenue of the Americas
34th Floor
NEW YORK NY 10020

Re: K053172
Trade/Device Name: Universal-X (USA) or Krystal-X (Europe)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: May 4, 2006
Received: May 8, 2006

Dear Mr. Maurier:

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 STATEMENT

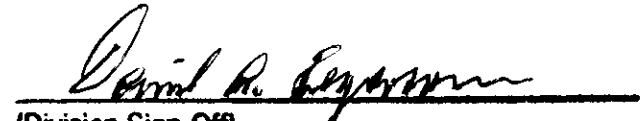
510(k) Number : K053172

Device name : UNIVERSAL-X

Indication for use : The UNIVERSAL-X digital system is designed to collect instant images of human oral tissue and teeth without the use of a conventional x-ray film.
It is used with a conventional X-ray tube and a Computer for dental radiographic imaging.
The Universal-X is covered with a single use disposable sheath and positionned in the oral cavity opposite the tooth the dentists wishes to xray.
The dental X-ray tube (which is not part of Universal-X) is pointed at the sensor and activated.
The emitted radiation from the X-ray tube is detected by the sensor and transmitted as a data stream to the computer system that the device is connected to.
In no case, it has to be used directly by the patient. So, it is used exclusively in a healthcare specific environment.
Similar devices have been in use in the USA since 1989, and are now well accepted by dentists.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053172