K083532

MAR 10 2009

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information: Dexcowin Co., Ltd
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Contact Person: Claude Yang (Yang Ho Dong)
Onbix Corporation
#708 Le-Meilluer Town, 837-19 Yeuksam-dong
Gangnam-gu, Seoul, Korea
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Date Summary Prepared: Nov 25, 2008

Device Name:
Trade Name(s): ADX4000-L, DX3000-L
Classification Name: X-Ray, Extraoral Source, Digital
Panel: Radiology
Product Code: MUH

Predicate Device Information:
K070811 DexcoWinA ADX4000

Device Description:
The ADX4000-L, DX3000-L are Cordless Portable Dental X-ray System operated by battery-powered and hand-held dental x-ray machine, This is a prescription device that can be used on pediatric and adult patients.

Intended Use:
The ADX4000-L, DX3000-L Cordless Portable Dental X-ray System is indicated for use only by trained and qualified dentists or dental technician for both adult and pediatric subjects for taking diagnostic extraoral dental X-rays using digital sensors.

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in its intended use and technological characteristics, including:

*indications for use
*technological characteristics
*performance properties

Summary of Testing:
This device meets consensus standards IEC 601-1, 60601-1, 60601-1-2, 60601-1-3, 60601-2-7 etc. Bench testing was also conducted to demonstrate performance specifications.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2009

DEXCOWIN Co., Ltd.
% Mr. Claude Yang, CEO
Onbix Corporation
#708 Le-Meilleur Town, 837-19 Yeuksam-dong, Gangnam-gu
Seoul, 135-937
SOUTH KOREA

Re: K083532
Trade/Device Name: ADX4000-L, DX30000-L
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: February 10, 2009
Received: February 12, 2009

Dear Mr. Yang:

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 (PMA), 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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, 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.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083532

Device Name: ADX4000-L, DX3000-L

Indications for Use:

The ADX4000-L, DX3000-L Cordless Portable Dental X-ray System is indicated for use only by trained and qualified dentists or dental technician for both adult and pediatric subjects for taking diagnostic extraoral dental X-rays using digital sensors.

Prescription Use _____X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(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 K083532

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