MAR 1 0 2006

K060178

EXHIBIT 2

510(k) Summary

GENDEX DENTAL SYSTEMS
901 West Oakton St.
Des Plaines, IL 60018-1884
1.888.275.5286
Fax 1.847.550.1322
Contact: John Miller, Director of RA/QA
January 17, 2006

1. Identification of the Device:
   Proprietary-Trade Name: VixWin Pro
   Classification Name/Product Codes: Picture archiving and communications system, 90 LLZ or System, x-ray, extraoral source, digital Product Code MUH
   Common/Usual Name: Dental Image Management System

2. Equivalent legally marketed device: DentalEye 2, K012439 and KaVo ERGOcom®/ERGOcam® K050744.

3. Indications for Use (intended use): VixWin PRO controls capture, display, treatment, analysis and saving of X-ray digital images from DenOptix®, Visualix®/GX-S, Orthoralix 9200 DPI and DDE digital imaging systems produced by Gendex. It can also handle other types of digital images, e.g. color images from an intraoral or extraoral dental camera, such as the Gendex Concept IV series, or images acquired by digitizing film with a flat bed scanner

4. Description of the Device: VixWin is a software program for general dental and maxillo-facial diagnostic imaging. It controls capture, display, treatment, analysis and saving of x-ray digital images from DenOptix ®, Visualix ® / GX-S, KaVo Dig eXam, Orthoralix DPI & DDE series imaging systems by Gendex ®. It can also handle other types of images acquired by digitizing film with a flat bed scanner, or color images from an intraoral or extraoral dental camera such as the AcuCam Concept IV and eZ1 series. When properly installed in your computer, VixWin lets you:

   - Control scanning and intake of x-ray images from image plates with the DenOptix scanner (*).
   - Control the direct capture of x-ray images from the intraoral sensor Visualix / GX-S, KaVo Dig eXam, Orthoralix DPI & DDE series systems (*).
   - View and capture color images from certain cameras, such as a dental camera, via a suitable video capture card (*).
   - Export and import digital images (such as those obtained by scanning a film) in several standard file formats.
   - Process images with dental specific tools, to enhance their diagnostic value.
   - Analyze and manipulate images in order to gather additional diagnostic information which may not be immediately apparent on initial visual inspection.
   - Create a database of patients and easily store images in patient folders..

Note (*): provided that the relevant hardware is available and properly configured and connected with your computer.

5. Safety and Effectiveness, comparison to predicate device:

Description	**DentalEye 2, K012439**	**KaVo ERGOcom® /ERGOcam® K050744**	**VixWin Pro**
Implementation	Software only	Hardware and Software supplied	Software only
Host platform	Intel or AMD based Personal Computer	PC Pentium, 1800 MHz or higher.	PC
Operating system	Windows 95 Windows 98 Windows ME Windows 2000 Windows NT	Windows 2000, Windows XP. And Microsoft .NET Framework.	Windows 98, 2000 and XP®
Host RAM	32 MB minimum	256 MB	32 MB
Host Magnetic Storage	At least 500 MB	Sufficient hard disk space to store imaging data., Usually 20 GB	4 GB minimum, 9 GB or more recommended.
Host Floppy Drives:	Not required	Not required	Not required
CD ROM	Yes (for installation)	Yes (for installation)	Yes (for installation)
Host Processor Speed	Pentium II 233 MHz or better	PC Pentium, 1800 MHz or higher.	Pentium 133 Mhz, 300 Mhz or faster recommended
Host Monitor Size	Any VGA or better PC color monitor	XGA or better, 15" or 19" Touch Display.	SVGA, XGA recommended
Display Resolution	Minimum 800 X 600 Recommended 1024 X 768	Screen resolution 1024 X 768, with min. true color depth (32 bit).	800 x 600 true color, 1024 x 768 true color recommended.
User Display Preferences	Yes	Yes	Yes
USB and S Video support	NO	Yes	Yes
Receive Images from other Systems	Yes	Yes	Yes
Images Displayed	Dental X-Rays, Intraoral Images, Extraoral Images (face, etc)	Dental X-Rays, Intraoral Images, Extraoral Images (face, etc), Entertainment (TV) for patients, Instructional Video, Patient Administration.	Dental X-Rays, Intraoral Images,
Safety Standards	Not applicable. Software only supplied.	UL/CSA standards for safety met.	Not applicable. Software only supplied.

6. Conclusion: In all important respects, the VixWin Pro is substantially equivalent to one or more predicate systems, including the one named above. This is based on testing to verify compliance with product specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2006

GENDEX Dental Systems
% Mr. Daniel Kamm, P.E.
Principal Consultant
P.O. Box 7007
DEERFIELD IL 60015

Re: K060178
Trade/Device Name: VixWin Pro
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: MUH and LLZ
Dated: January 19, 2006
Received: January 27, 2006

Dear Mr. Kamm:

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 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

Indications for Use

510(k) Number (if known): K060178

Device Name: VixWin Pro

Indications For Use: VixWin PRO controls capture, display, treatment, analysis and saving of X-ray digital images from DenOptix®, Visualix®/GX-S, Orthoralix 9200 DPI and DDE digital imaging systems produced by Gendex. It can also handle other types of digital images, e.g. color images from an intraoral or extraoral dental camera, such as the Gendex Concept IV series, or images acquired by digitizing film with a flat bed scanner.

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)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060178