APR 2 1 2005 K050744

EXHIBIT 2

510(k) Summary

KaVo America Corporation
340 East Main Street
Lake Zurich, Illinois 60047
Tel: 847 / 550 - 6800
Fax: 847 / 550 - 6825
Contact: John Miller, Director of RA/QA
March 7, 2005

1. Identification of the Device:
   Proprietary-Trade Name: KaVo ERGOcom®/ERGOcam®
   Classification Name: Dental Hand Instrument, Laser Fluorescence Caries Detection Device, 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.

3. Indications for Use (intended use): For acquiring, viewing, handling, and storage of dental color images and radiographs.

4. Description of the Device: KaVo ERGOcom®/ERGOcam® system consists of four main components:
   - The ERGOcom® Video control box.
   - One of two versions of the ERGOcam® Cameras: The ERGOcam® 3 of the ERGOcam® 4 camera.
   - A video display, flat panel color from 15 to 19" with touch screen control
   - A PC compatible computer with the KaVo Device Interface System Software installed. The Device Interface System has the following components:
     1. CCCDIS. The CCCDIS software is used to administer and configure the software components in the KaVo Device Interface System .The CCCDIS acts as the interface of the KaVo Device Interface System with third party applications
     2. ERGOcam Control The ERGOcam Control software is used to configure individual parameters of the ERGOcam 4
     3. ERGOcom Control The ERGOcom Control software is used for the PC-assisted status display, configuration and service support of the ERGOcom 3.
     4. ERGOvideo Control The ERGOvideo Control software is used for generating and displaying video imaging data created with ERGOcom 2 / ERGOcom 3 andERGOcam 3 / ERGOcam 4 .
     5. ERGOcam Viewer The ERGOcam Viewer is used for demonstrating the use of the ERGOvideo Control, ERGOcam Control and ERGOcom Control. The ERGOcam Viewer is used to store and administer imaging data that have been generated with the software components referred to above.
     6. VirtualCom2 VirtualCom2 is used to convert the foot starter and camera cradle signals from ERGOcom 3 to a format that is compatible with ERGOcom 2 .These signals are only used to control program modules within a practice management software that

allows the recording of images with a KaVo intraoral camera, thereby meeting the interface specification for the serial interface of ERGOcom 2.

The intraoral camera emits video signals which generate an image of the area under inspection (the patient's oral cavity for instance) on a screen or other visual display medium. The generated image is used for the patient's information and to support the diagnosis.

5. Safety and Effectiveness, comparison to predicate device:

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

6. Conclusion: In all important respects, the KaVo ERGOcom®/ERGOcam® Dental Image System is substantially equivalent to one or more predicate systems, including the one named above. The system has been thoroughly tested to IEC/UL/CSA standards including electrical safety and electromagnetic compatibility and has been found to comply with those standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1 2005

KaVo America Corporation
% Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K050744
Trade/Device Name: KaVo ERGOcom® / ERGOcam®
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: March 17, 2005
Received: March 25, 2005

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): K050744

Device Name: KaVo ERGOcom®/ERGOcam®

Indications For Use:

For acquiring, viewing, handling, and storage of dental color images and radiographs.

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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K050744