AUG 2 - 2005

K042394

EXHIBIT 2

510(k) Summary

KaVo America Corporation
340 East Main Street
Lake Zurich, Illinois 60047
Toll Free: 800 323 8029
Tel: 847 / 550 - 6800
Fax: 847 / 550 - 6825
e-mail: info@kavousa.com
Contact: John Franz, President
August 30, 2004

1. Identification of the Device:
   Proprietary-Trade Name: KaVo DIAGNOdent® Perio Tip
   Classification Name: Dental Hand Instrument, Laser Fluorescence Caries Detection Device, Product Codes EJB, NBL
   Common/Usual Name: Periodontal Probe

2. Equivalent legally marketed device: DIAGNOdent® K983658 and DETECTAR, K023367 .

3. Indications for Use (intended use): For use as an aid in the detection and localization of subgingival dental calculus.

4. Description of the Device: This submission is for a modification of a device system cleared under K983658, the DIAGNOdent®. The modification is in the form of a new accessory probe tip which can be connected to the unmodified DIAGNOdent® electronics system. The probe tip is longer and more slender to allow for the periodontal use. In-vitro and preclinical studies have shown that that laser fluorescence is correlated with materials in calculi and concrements [a,b]. The researchers identified the method of subgingival calculi detection to be a reproducible, objective method for assessing the root surface[b]. Although the intensity of the detection was influenced by surrounding media, the differences between cementum and calculus was highly significant in media like air, electrolytic solution and blood[a].

   a. M. Folwaczny, R. Heym, A. Mehl and R. Hickel, "Subgingival Calculus detection with Fluorescence induced by 655 nm InGaAsP Diode Laser Radiation", J. Periodontol, June 2002, p 597-601
   b. F. Krause, A. Braun, M. Frentzen, "The possibility of detecting subgingival calculus by laser-fluorescence in vitro", Lasers Med. Sci. (2003) 18: 32-35

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5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	DIAGNOdent® K983658	DETECTAR, K023367	DIAGNOdent® Perio Tip
Indications for use	Detection of Dental Caries	Detection of subgingival dental calculus	Detection of subgingival dental calculus
Probe technology	Fiber Optic	SAME	SAME
Light Source	655 nm <1 mw Laser	Two LEDs. The first is in the red area of the visible spectrum (RED-LED) and shows a wavelength peak at 635 in a band between 600 and 670nm. The second LED is in the near infrared spectrum (NIR-LED) and shows a wavelength peak at 880 nanometers in a band between 800 and 900nm.	655 nm <1 mw Laser
Returned light	Fluorescence	Not specified. (proprietary)	Fluorescence
Sterilization	Probe tip only, autoclave	SAME	SAME
Target population	Dentists' offices	SAME	SAME

6. Conclusion: In all important respects, the DIAGNOdent® Perio Tip is substantially equivalent to the DIAGNOdent® K983658 and DETECTAR, K023367. This conclusion is based on indications for use, in-vitro, and clinical studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 - 2005

Kavo America Corporation
C/O Mr. Daniel Kamm
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K042394
Trade/Device Name: DIANGOdent® Perio Tip
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: NBL
Dated: July 27, 2005
Received: July 28, 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 (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 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 (240) 276-0115. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042394

Indications for Use

510(k) Number (if known):

Device Name: DIAGNOdent® Perio Tip

Indications For Use:

For use as an aid in the detection and localization of subgingival dental calculus.

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042394