K051909

OCT 2 1 2005

EXHIBIT 2

510(k) Summary

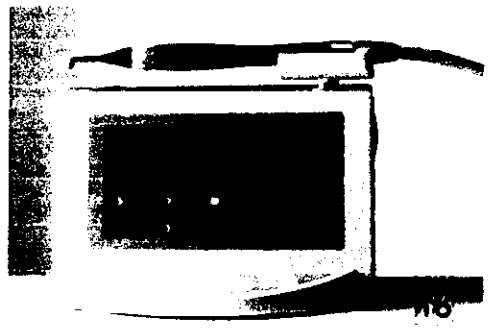
KaVo Dental Corporation
340 East Main Street
Lake Zurich, Illinois 60047
Toll Free: 800 323 8029
Tel: 847 / 550 - 6800
Fax: 847 / 550 - 6825
e-mail: info@kavousa.com
Contact: John Miller, Director of RA/QA
July 11, 2005

1. Identification of the Device:
   Proprietary-Trade Name: KaVo DIAGNOdent® 2190
   Classification Name: Dental Hand Instrument, Laser Fluorescence Caries Detection Device, Product Codes NTK
   Common/Usual Name: Laser fluorescence caries detection device

2. Equivalent legally marketed device: DIAGNOdent® 2095, K983658.

3. Indications for Use (intended use): For use as an aid in the diagnosis of dental caries.

4. Description of the Device: This submission is for a modification of a device system cleared under K983658, the DIAGNOdent® 2095. The modification is in the form of a new method of packaging the device, in the form of a pen-like device instead of the former electronic unit with a fiber optic probe.

Predicate DIAGNOdent® 2095	DIAGNOdent® 2190
	

5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	DIAGNOdent® 2095, K983658	DIAGNOdent® 2190
Indications for use	For use as an aid in the Diagnosis of Dental Caries	SAME
Probe technology	Fiber Optic with sapphire tip.	Probe is integrated into the body of the hand held unit, with sapphire tip.
Light Source	655 nm <1 mw Laser	650 nm, 190 nw maximum average radiant power
Laser power class	Class II	Class I
Returned light	Fluorescence	Fluorescence
Sterilization	Probe tip only, autoclave	SAME
User interface	Numeric and audible tones LED numbers	SAME except LCD numbers
Power source	6- AA Alkaline battery	1- AA Alkaline battery
Target population	Dentists' offices	SAME

6. Conclusion: In all important respects, the DIAGNOdent® 2190 is substantially equivalent to the DIAGNOdent® K983658. This conclusion is based on indications for use, bench, in-vitro, and clinical studies, as well as EMC and electrical safety testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 1 2005

KAVO AMERICA
C/O Daniel Kamm
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deer Field, Illinois 60015

Re: K051909
Trade/Device Name: DIAGNODENT
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence caries detection device
Regulatory Class: II
Product Code: NBL
Dated: October 12, 2005
Received: October 13, 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.

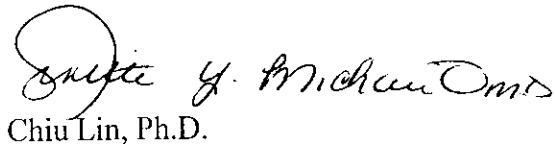
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

Indications for Use

510(k) Number (if known): K051909

Device Name: DIAGNOdent® 2190

Indications For Use:

For use as an aid in the diagnosis of dental caries.

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)

Susan Runyon

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

510(k) Number: K051909