JUL 9 2003

K031868

EXHIBIT 2

KaVo America Corporation
340 East Main Street
Lake Zurich, Illinois 60047
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Contact: John Franz, President

June 12, 2003

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: KaVo PROPHYpearls
   Classification Name: HANDPIECE, AIR-POWERED, DENTAL, Product Code EFB
   Common/Usual Name: Cleaning powder for use with dental handpiece

2. Equivalent legally marketed device: This product is similar in design and identical in function to PROPHYflex 2 (K973876) (powder).

3. Indications for Use (intended use): PROPHYpearls is a powder intended for use in removing plaque deposits and stains from teeth by projecting a mixture of water, air, and calcium carbonate onto tooth surfaces.

4. Description of the Device: This submission is for a modification of a device system cleared under K973876, the PROPHYflex 2 Dental Device. The predicate system consists of a handpiece and powder combination which is intended for use in removing plaque deposits and stains from teeth by projecting a mixture of water, air, and sodium bicarbonate onto tooth surfaces. The modification involves changing the powder from sodium bicarbonate to calcium carbonate. Calcium carbonate is a substance which is inherently biocompatible, and studies have shown that the calcium carbonate powder does an equal or better job of removing plaque. Calcium carbonate is recognized in the Code of Federal Regulations as a food substance generally recognized as safe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 2003

KaVo America Corporation
C/O Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K031868
Trade/Device Name: PROPHYpearls
Regulation Number: 21 CFR 872.6030
Regulation Name: Oral Cavity Abrasive Polishing Agent
Regulatory Class: I
Product Codes: EJR, EFB
Dated: June 16, 2003
Received: June 26, 2003

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 (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K031868

Device Name: .

Indications for Use: PROPHYpearls is a powder intended for use in removing plaque deposits and stains from teeth by projecting a mixture of water, air, and calcium carbonate onto tooth surfaces.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)

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

510(k) Number: K031868