K032081

JUL 24 2003

EXHIBIT 2

510(k) SUMMARY: KaVo Everest® ZS-Blank

This 510(k) summary of safety and effectiveness for KaVo Everest® ZS-Blank material is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: KaVo America Corporation

Address: 340 East Main Street
Lake Zurich, IL 60045

Manufacturer: KaVo Elektrotechnisches Werk GmbH,
D-88293, Leutkirch im Allgau
Germany

Contact Person: Ms. Jennifer Pottala

Telephone: 847-550-6800 847-550-6825 (Fax) 800-323-8029

Preparation Date: June, 2003 (of the Summary)

Device Name: KaVo Everest® ZS-Blank
Common Name: Dental Frame Material for Dental Prosthesis

Classification: Porcelain, powder for clinical use
21 CFR 872.6660
Class II medical device
Product Code: EIH
Panel: 76

Predicate devices: KaVo Everest G-Blank K030607 and Vita inCeram Zirconia, K022996, among others.

Device description: The KaVo Everest® ZS-Blank is a pre-formed material for use by dental laboratories in filling orders/prescriptions for dental prosthetics

Indications: The KaVo Everest® ZS-Blank is used in the manufacture of dental prosthetics.

KaVo proposes that the materials distributed within the United States be labeled:

"CAUTION: Federal (US) law restricts the sale of this device to, or on the order of, licensed professionals."

Performance Data: None required. The claim of substantial equivalence is based on comparisons of formulations and intended uses of the KaVo devices to legally marketed predicates and to the IDENTIFICATION of porcelain powders in 21 CFR 872.6660.

CONCLUSION: Based on the information in the notification KaVo America believes that The KaVo Everest® ZS-Blank is substantially equivalent to cited legally marketed predicates and to the IDENTIFICATION in the classifying regulation (21 CFR 872.6660).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2003

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

Re: K032081
Trade/Device Name: KaVo Everest® ZS-Blank
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Codes: EIH
Dated: July 01, 2003
Received: July 08, 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.

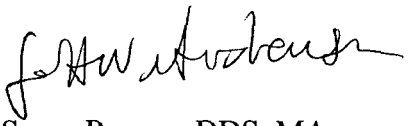
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



for 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 K032081

Device Name: KaVo Everest® ZS-Blank .

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

R S Betz DDS for Dr. K. Mulay
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K032081