OCT - 2 2003

510(k) Summary of safety and effectiveness

K032234

Applicant: MK-dent® GmbH
Eichenweg 7B
22941 Bargteheide, Germany

Contact: Dr. Martina Günderoth
C.R.C. Partnerschaftsgesellschaft
Katharinenstr. 5
23554 Lübeck, Germany
Phone: +49 (451) 388 2864 / Fax: +49 (451) 388 2867
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Device Name: MK-dent® High Speed Dental Handpiece, Models HS4021K, HS4011K, HS4012K, HS6021K, HS6011K, and HS6012K

Common Name: Handpiece, air-powered, dental

Classification Name: Dental handpiece

Device Class: Class I

Product Code: 76 EFB

Code of Federal Regulations: 21 CFR 872.4200

Indications for Use: The device is an air-powered dental handpiece providing light through a glass optic rod for use by a trained professional in general dentistry.

Predicate Device Name: KaVo Dental Handpiece, Series 630 and 640 (K 760929)
MK-dent® High Speed Dental Handpiece (K 021250)

Description of Device:
The MK-dent® HS Handpiece shares virtually all specifications and design characteristics of the predicate devices. This was done intentionally by the designers and engineers. Only few minor changes implemented to the predicate device make the MK-dent® Handpiece more convenient to use but do not affect the performance, safety or effectiveness of it.

Substantially Equivalence - Safety and Effectiveness:
In all respects, the MK-dent® Handpiece is substantially equivalent to one or more air-powered dental handpieces currently marketed in the USA. The handpiece is constructed of materials of the same specifications as the predicate device to ensure biocompatibility. The handpiece conforms to applicable ISO standards. The ability to repeatedly adequately sterilize the device has been confirmed by validation protocol.

Voluntary standard compliance:

- ISO Standard 7785-1: High speed dental turbines
- ISO Standard 1797: Shank dimensions
- ISO Standard 3964: Coupling device
- ISO Standard 27785: Sound level
- ISO Standard 27785: Water coolant
- ISO Standard 1797: Spindle strength

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

MK-Dent Gmbh
C/O Dr. Martina Gunderoth
C.R.C. Partherschaftsgesellschaft
Katharinenstr. 5
23554 Lubeck, Germany

Re: K032234
Trade/Device Name: MK-Dent High Speed Dental Handpiece, Models HS4021k KS4011K, HS4012K, HS6021K, HS6011K, and HS6012K
Regulation Number: 872.4200
Regulation Name: Dental handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: June 24, 2003
Received: July 21, 2003

Dear Dr. Gunderroth:

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. 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/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

3. Indications for Use

510(k) Number K032234

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter Mulley for MSR

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

510(k) Number: K032234

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