K080939

510(k) SUMMARY

Applicant and Owner	W & H Dentalwerk Buermoos GmbH JUL 29 2008 Ignaz-Glaser-Strasse 53 A - 5111 Buermoos Austria Tel.: +43-6274-6236-397 Fax: +43-6274-6236-234
Contact Person	Gabriele Wienbeck
Date of Preparation	21.03.2008
Device Name	Surgical straight handpiece SI-11 LED G Surgical contra-angle handpiece WI-75 LED Mikro saw handpieces S-8 R, S-8 O, S-8 S
Classification Name	Handpiece, rotary bone cutting
Regulation Number	21 CFR872.4120
Product Code	KMW
Predicate Device	Surgical contra-angle handpieces, K011061 Saw handpieces K052741
Device Description	Surgical handpieces and Mikro saw handpieces have been designed to transmit the rotational movement of the motor axle to the shank of a bur or a saw blade which will be inserted into the output end of the handpiece. They fit all surgical drive units and surgical motors with a coupling system according to ISO 3964. The user manual points out the recommendations for the different handpiece types covered by this application.
Intended Use:	Surgical treatment of dental hard tissue in oral and maxillo-facial surgery
Technological Characteristics	The Surgical contra-angle handpieces represents revised versions of the predicate device. The main technical characteristics have been retained unchanged. New : The redesigned handpieces contain their own integrated generator to provide LED light to the operating area.
Comparison of the device to the predicate device	The intended use, technological characteristics, performance parameter and material are very similar to the predicate device. The devices are substancially equivalent to the predicate devices.
Performance Testing	Bench testing results demonstrate substancially equivalence
Clinical Testing	Clinical data were not needed for this modification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Gabriele Wienbeck
Regulatory Affairs
W&H Dentalwerk Buermoos GmbH
Ignaz-Glaser-Straße 53
P.O. Box 1,
5111 Bürmoos
AUSTRIA

JUL 29 2008

Re: K080939
Trade/Device Name: Surgical Handpieces and Mikro Saw Handpieces
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: KMW
Dated: June 25, 2008
Received: July 21, 2008

Dear Ms. Wienbeck:

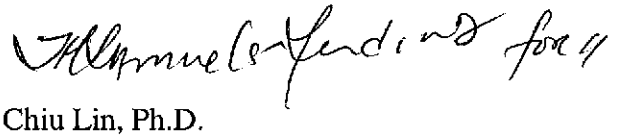
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

INDICATION FOR USE

510(k) (if known): K080939

Device Name: Surgical handpieces and Mikro saw handpieces

Indication for Use:

Surgical treatment of dental hard tissue in oral and maxillo-facial surgery

Prescription Use X AND/OR Over- The –Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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