K100600

JUL - 9 2010

510(k) SUMMARY

Applicant and Owner	W&H Dentalwerk Buermoos GmbH Ignaz-Glaser-Strasse 53 A - 5111 Buermoos Austria Tel.: 0043 -6274 / 6236 -297 Fax: 0043 -6274 / 6236 -234
Contact Person	Johann Georg SCHARL
Date of Submission	March 1st, 2010
Device Name	Prosthodontic Screwdriver IA-400
Classification Name	Handpiece, Direct Drive, Ac-Powered
Regulation Number	21 CFR872.4200
Product Code	EKX
Predicate Devices	- "implantMED SI-915", cleared by W&H Dentalwerk Buermoos under K052741 + "WS-75 E/KM", cleared by W&H Dentalwerk Buermoos as an accessory to the "implantMED SI-915" in file K052741 - Cordless Endo Handpc. "ENTRAN", W&H Dentalwerk Buermoos, K090931
Device Description	The cordless Prosthodontic Screwdriver IA-400 consists of the cordless drive IA-40H, the contra-angle attachment IA-80 and a key pad (finger switch). The drive is fitted out with a 3.7 V Li-Ion battery, which can be re-charged using the provided charging station. The drive and the contra-angle attachment are connected via a special coupling, based on ISO 3964. By means of the different buttons on the drive the user controls the various settings, such as ON, forward/reverse and the torque. The attached key pad (finger switch) allows starting and stopping the screwdriver´s rotation. The handpiece´s application is intended in dentistry.
Intended Use:	The drive unit is an electrically controlled screwdriver with adjustable torques to tighten and unscrew prosthodontic screws. Consisting of: - Cordless drive unit - Mechanical transmission instrument 80:1

Technological Characteristics	W&H´s "Prosthodontic Screwdriver IA-400" represents a device combining the technical principle of the cordless ENDO-Handpiece "ENTRAN" (510(k) no. K090931) with a special field of applicability of W&H´s drive unit "implantMED SI-915", provided with the contra-angle handpiece attachment type WS-75 E/KM (both cleared for market under 510(k) K052741). The advantage of the new product is based, above all, on the fact that the "Prosthodontic Screwdriver IA-400" was designed for a detail of the "implantMED´s" applicability. So it offers advantages with respect to usability and flexibility: cordless, less weight, smaller size, better balanced, ergonomically designed.
Comparison of the device to the predicate device	The intended purpose of the predicate device "implantMED" covers the new device´s intended use; "implantMED´s" performance parameters are very similar in this respect to the new device´s ones. The technological characteristics and materials, on the other hand, are very similar to those of the predicate device "ENTRAN". With respect to the functions considered as intended use, the new device can be judged to be substantially equivalent to the predicate devices.
Performance Testing	W&H´s Prosthodontic Screwdriver IA-400 was developed and is produced under consideration of all applicable technical standards and quality management directives. The product´s conformance with the applicable technical standards was verified in the course of type testing. Bench testing results demonstrated substantially equivalence. Perfect functionality and accuracy of all serial devices are controlled in the final step of production. Corresponding certificates and the application of the CE-mark give evidence of the product´s high quality.
Clinical Testing	Clinical data were not needed for this new product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
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Mr. Johann G. Scharl
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Re: K100600
Trade/Device Name: Prosthodontic Screwdriver IA-400
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: June 25, 2010
Received: June 25, 2010

Dear Mr. Scharl:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 100600

Indications for Use

510(k) number:

not known yet

Device Name:

Prosthodontic Screwdriver IA-400

Indication for Use:

The drive unit is an electrically controlled screwdriver with adjustable torques to tighten and unscrew prosthodontic screws.
Consisting of: - Cordless drive unit
- Mechanical transmission instrument 80:1

Prescription Use _____X_____ (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use _____ (Part 21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulley for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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