JAN 14 2010 K083811

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 Preparation	December 19th, 2008
Device Name	Handpiece RA-5 "ANESTO"
Classification Name	Spring Powered Jet Injector
Regulation Number	21 CFR872.4475
Product Code	EGM
Predicate Devices	"IntraFlow HTP", Pro-Dex Micro Motors Inc., 510(k) exempt "Cyberjet", Intra Vantage Inc., K964802
Device Description	RA-5 "ANESTO" is a handpiece, which, on the one hand, is provided with a coupling system according to ISO 3964. This coupling allows the handpiece's attachment onto a corresponding dental motor, for transmitting the motor's rotational movement to the attached intraosseous injection needle, intended to perforate cortical bone. On the other hand, it was designed for being equipped with an anesthetic cartridge acc. ISO 11499, volume 1.7 or 1.8ml. After having perforated the bone, this cartridge's anesthesia can be administered locally in the spongiosa by means of a manually-operated dosage lever. "ANESTO's" application is intended in dentistry.
Intended Use:	Drilling system to perforate cortical bone in order to administer local anesthesia in spongiosa; application in dentistry.
Technological Characteristics	The Handpiece RA-5 "ANESTO", represents a revised and improved version of the predicate device. The main technical characteristics have been retained unchanged. New: "ANESTO" is designed to be attached on and driven by a dental micro motor (air or electric motor), instead by the integrated air-supplied driving system of the predicate device. Furthermore, the handpiece's shape and ease of operation have been improved for more user-friendliness.
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 new device is substantially equivalent to the predicate devices.
Performance Testing	Bench testing results demonstrate substantially equivalence
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 W-O66-0609
Silver Spring, MD 20993-0002

JAN 1 4 2010

Mr. Johann G. Scharl
Regulatory Affairs Manager
W & H Dentalwerk Buermoos GmbH
53 Ignaz-Glaser-Strasse
Buermoos
Austria 5111

Re: K083811
Trade/Device Name: Handpiece RA-5 "ANESTO"
Regulation Number: 21CFR 872.4475
Regulation Name: Spring-Powdered Jet Injector
Regulatory Class: II
Product Code: EGM
Dated: January 7, 2010
Received: January 11, 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, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number: K083811

Device Name: Handpiece RA-5 "ANESTO"

Indication for Use:

Drilling system to perforate cortical bone in order to administer local anesthesia in spongiosa.
Application in dentistry.

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)

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

510(k) Number: K083811