K092231

NOV 24 2009

>>Summary

510(k) Summary as required by section 807.92(c)

Date: 10/29/09

Submission Applicant:
gebdi Dental-Products GmbH
Industriestr. 3a
78234 Engen

Phone: xx49-7733-9410-0
Fax: xx49-7733-6434
E-mail: info@gebdi-dental.com

Application corresondent/Contact person:
gebdi Dental-Products GmbH
Jasmin Jung
Industriestr. 3a
78234 Engen

Phone: xx49-7464-96600
Fax: xx49-7462-924128
E-mail: j.jung@bell-qm.de

Trade name:
gebdi Tribos 501
K-Number: K092231

Common name:
Preformed plastic tooth / artificial PMMA teeth

Classfication name:
Preformed plastic denture tooth, Dental (21 CFR 872.3590 - EBF)

Substantial Equivalence Claim:
K790439 - Vivadent (USA) Inc.

Description of the Device:
gebdi Tribos 501 artificial teeth devices are chemically based on polymethacrylate-polymers and their chemical properties. These preformed plastic dentures are used when fabricating any kind of dental restauration like long-term implants, provisional restaurations and/or removable dental prostheses at the dental laboratory only.

Application range (dental laboratory use only!):
- implant retained dentures
- provisional restaurations
- hybrid dentures
- partial dentures
- complete dentures
- hybrid dentures

Indications for Use:
gebdi Tribos 501 are preformed plastic denture teeth as a prefabricated device, composed of materials such as methyl methacrylate, that are intended for use as a tooth in a denture

Comparison with P.D.

The gebdi product is similiar to the P.D. in terms of technical characteristics, design, Indications for Use, target population, where it is used, performance, biocompatibility characteristics as well as sizes and configurations. **Therefore the gebdi product can be deemed substantially equivalent and safe and effective for its indicated use.**

Summary

The presented data that was conducted on the gebdi products shows in its results and in comparison to the predicate devices that the products are absolutely safe and effective for their intended use and do not raise any questions regarding safety and effectiveness. All models that are covered by this 510(k) premarket notification have been on the market in Europe for many years with no device failures. The used materials are well researched and do not raise any kind of question regarding safety and effectiveness of the finished 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

NOV 24 2009

Mr. Thomas Biskupski
Managing Director
gebdi Dental-Products GmbH
Industriestra 3A
Engen BaWu
GERMANY 78234

Re: K092231
Trade/Device Name: gebdi Tribos 501
Regulation Number: 21 CFR 872.3950
Regulation Name: Glenoid Fossa Prosthesis
Regulatory Class: II
Product Code: ELM
Dated: November 12, 2009
Received: November 12, 2009

Dear Mr. Biskupski:

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.

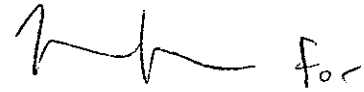
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



Susan Runner, D.D.S., M.A.
Acting 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) Number: K092231

Device Name:
gebdi Tribos 501

Indications for use:
A preformed plastic denture tooth is a prefabricated device, composed of materials such as methyl methacrylate, that is intended for use as a tooth in a denture.

The devices are offered in non-sterile condition.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of DCRH, Office of Device Evaluation (ODE)

Robert S Betz DDS for Dr. Kevin Mulley
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092231