

K120404

MAY 21 2012

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510(k) Summary

Merz Dental GmbH artegral HD preformed plastic denture teeth

Submitter

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Date of Summary: April 20, 2012

Device Name

Proprietary name: artegral HD
Common name: Denture teeth
Classification name: Denture, plastic, teeth (21CFR 872.3590 Product Code ELM)

Predicate Device

K030588, Merz Dental GmbH artegral and Polystar Selection Denture Plastic Teeth

Device Description

artegral HD are preformed posterior plastic teeth made from an Interpenetrated Polymer Network (IPN) of polymethymethylmethacrylate (PMMA) with two modifications. The artegral HD tooth neck is made from Organic Modified Polymer

Network (OMP-N) and the incisal and dentine portions of the tooth are made from Highly Modified Polymer-Network (HMP-N). OMP-N has added insoluble PMMA spheres, and HMP-N has added amorphous silicon dioxide nanoparticles and fluorapatite. The artegral HD teeth comply with all the requirement of ISO 22112:2005 *Dentistry – Artificial teeth for dental prostheses*. The additives in artegral HD teeth are known biocompatible materials.

Intended Use

The *artegral* HD (high definition) teeth have the same intended use as *artegral* posterior preformed plastic denture teeth cleared in K030588. As described below, the intended use for artegral HD plastic teeth is described in more detail than the predicate artegral plastic teeth.

Artegral HD posterior preformed plastic denture teeth intended use:

- Supra construction for combined, fixed removable dental prostheses
- Hybrid construction for implant-supported dental prostheses
- Cover denture
- Total prostheses
- Model cast prostheses
- Partial dentures

Artegral posterior preformed plastic teeth intended use:

- Denture teeth

Technological characteristics and substantial equivalence

The device is comparable in chemical composition to the predicate device.

The device is similar in size, shape, color and usage to the predicate device.

Both the device and the predicate device comply with the physical characteristic requirements of ISO 22112:2005 *Dentistry – Artificial teeth for dental prostheses*.

Performance Testing

The artegral HD teeth were tested according to ISO 22112:2005 *Dentistry – Artificial teeth for dental prostheses* and shown to comply with all the requirements of the standard.

Test of the artegral HD teeth was performed according to ISO/CD 20795-1 “Dentistry – Base polymers – Part 1: Denture base polymers” (Type 1:Class 1) to judge if there will be a risk from residual methyl methacrylate monomer which can be eluted from the teeth in the oral cavity. The average concentration of residual MMA was well below the limit given in the standard.

Testing for biocompatibility was also performed as follows and all test results were acceptable:

Examination of an Eluate of HMP-N for Cytotoxic Properties in a Cell Culture Test, according to USP 29 and ISO 10993 part 5, Elution Test

Screening for Eye Irritancy Potential of HMP-N in the Chorioallantoic Membrane Assay

Examination of HMP-N in the Skin Sensitization Test in Guinea Pigs According to Magnusson and Kligman (Maximization Test), according to EC method B.6. (96/54/EC), OECD guideline 406 and EN/ISO/DIN 10993-10.2

Clinical Performance

The determination of substantial equivalence is not based on clinical performance data.

Other Information

No other information was deemed necessary by FDA.

Conclusions

artebral HD is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

Merz Dental GmbH
C/O Mr. Richard G. Hunter
Principal
Washington Regulatory Consultants
5616 Mariola Place, NE
Albuquerque, New Mexico 87111

MAY 21 2012

Re: K120404
Trade/Device Name: Artegral HD
Regulation Number: 21 CFR 872.3590
Regulation Name: Preformed Plastic Denture Tooth
Regulatory Class: II
Product Code: ELM
Dated: May 10, 2012
Received: May 11, 2012

Dear Mr. Hunter:

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.

Page 2 – Mr. Hunter

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,



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

Indications for Use

510(k) Number (if known): K120404

Device Name: artegral HD

Indications for Use:

Artegral HD are posterior preformed plastic denture teeth for use in:

- supra construction for combined, fixed removable dental prostheses
- hybrid construction for implant-supported dental prostheses
- cover denture
- total prostheses
- model cast prostheses
- partial dentures

Prescription Use X
(21 CFR Part 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR Part 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

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