K134015

APR 1 1 2014

510(k) Summary

Merz Dental GmbH M-PM-Disc (Clear)

Submitter: Merz Dental GmbH
Eetzweg 20
Lutjenburg, Germany D-24321

Contact: Richard G. Hunter, MS, RAC
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Date of Summary: April 8, 2014

Trade Name: M-PM-Disc (Clear)

Regulation Name: Mouthguard

Regulation Class: Not Classified

Product Code: MQC

Predicate Devices: K062828 -- Mouthguard and Aligner Materials, DENTSPLY Intl.
K030588 -- artegral Denture Teeth, Merz Dental GmbH
K071548 -- M-PM-Disc (Tooth Colored), Merz Dental, GmbH

Device Description:

The Merz Dental MP-M-Disc (Clear) is a solid disc composed of a highly cross-linked homogenous combination of polymethylmethacrylate (PMMA) copolymers known as an Interpenetrated Polymer Network (IPN). This is the same material used in Merz Dental artegral Denture Teeth (K030588) and the Merz Dental M-PM-Disc (Tooth Colored) (K071548). The difference is that the MPM-Disc (Clear) PMMA does not have added pigments. The M-PM-Disc (Clear) PMMA contains polymethylmethacrylate cross-linked polymer based on methacrylic acid esters, residual peroxide and residual monomer up to a maximum of 1%. It is offered in sizes from 90 x15 mm to 114.8 x 25 mm. Bite splints are prepared from the disc using a milling technique.

Intended Use

The Mertz Dental GmbH M-PM-Disc (Clear) is indicated for the fabrication of removable bite splints such as mouthguards and nightguards.

Technological characteristics and substantial equivalence

The MP-M-Disc (Clear) has the same indications for use and configurations as the predicate devices. It also has the same composition (acrylic polymers) which meet the ISO requirements for physical properties and biocompatibility for these dental indications. The M-PM-Disc (Clear) and the predicate device differ in their method of fabrication. M-PM-Disc (Clear) is milled from solid PMMA whereas the predicate device (Mouthguard and Aligner Material, K062828) is thermoformed. Side-by-side comparisons of the properties of the M-PM-Disc (Clear) bite splint to the predicate is presented below in Table 1. Based on these comparisons, the MP-M-Disc (Clear) is not significantly different, and thus substantially equivalent, to the predicate devices.

Table 1: Comparison of M-PM-Disc (Clear) Bite Splint to Predicate Device

	M-PM-Disc (Clear)	**Mouthguard and Aligner Materials K062828**
Intended Use	Bite Splint/Mouthguard	Same
Composition	Acrylic Polymer (PMMA) Solid	Same
Colorants	None	Same
Fabrication Method	Milling	Thermoforming
Physical Properties	Meets applicable ISO Standard Tested to ISO 1567: Flexural Strength Limit: >65 MPa Flexural Modulus: >2000 MPa Water Absorption: < 40 g/mm3 Solubility: <7.5 mcg/mm3	Meets applicable ISO Standard
Biocompatibility	Compliance with ISO 10993-1	Same

Clinical and Non-Clinical Performance:

The M-PM-Disc (Clear) has not been tested clinically.

Both the M-PM-Disc (Clear) and the predicate devices are fabricated from PMMA. The PMMA used in M-PM-Disc (Clear) has been tested for biocompatibility and physical properties according ISO 10993-1 tissue contacting requirements. The testing was performed on a virtually identical PMMA--Merz Dental artegral plastic teeth, since the latter material is identical to that of M-PM-Disc (Clear) but has added tooth-color pigments. The material met the biocompatibility requirements of ISO 10993-1--in particular the material was non-cytotoxic, non-irritating and non-sensitizing. The M-PM-Disc (Clear) material, as represented by the PMMA (tooth colored) in Merz Dental artegral plastic teeth, also meets the requirements of ISO 3336:1996, Dentistry-Synthetic, Polymer Teeth).

The tests discussed above and in the non-clinical testing section indicate that the subject device is safe and effective for its intended use and performs as well or better than predicate device(s).

Conclusion:

The non-clinical testing results indicate that the subject device is safe and effective for its intended use and performs as well or better than predicate device(s). Therefore, the M-PM-Disc (Clear) is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 11, 2014

Mertz Dental GmbH
c/o Richard Hunter, MS, RAC
Principal
Washington Regulatory Consultants
5616 Mariola Place
Albuquerque, NM 87111

Re: K134015
Trade/Device Name: M-PM-Disc (Clear)
Regulation Number: None
Regulation Name: Mouthguard
Regulatory Class: Unclassified
Product Code: MQC
Dated: January 21, 2014
Received: January 23, 2014

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.

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 contact 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. 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,

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K134015

Device Name: M-PM-Disc (Clear)

Indications for Use:

The Merz Dental GmbH M-PM-Disc (Clear) is indicated for the fabrication of removable bite splints such as mouthguard and nightguards.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(21 CFR Part 801 Subpart D) (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)

Michael E. Adjodha -S
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Page 1 of __1_