Merz Dental GmbH
% Richard Hunter
Principal
Washington Regulatory Consultants, LLC
5616 Mariola PI NE
Albuquerque, Minnesota 87111

December 18, 2018

Re: K173124
Trade/Device Name: PEEK Biosolution
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: September 28, 2017
Received: September 29, 2017

Dear Richard 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting 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): K173124

Device Name: *PEEK Biosolution*

Indications for Use:

PEEK Biosolution is intended to be used for the fabrication of permanent dental restorations using CAD/CAM techniques. These are:

- Fully anatomical crowns and bridges (max. 2 pontics and min. 13 mm² connector cross-section)
- Crown copings and bridge substructures for composite veneering (max. 2 pontics and min.13 mm² connector cross-section))
- Telescopic primary and secondary crowns and frameworks
- Secondary bar structures on primary bars made of titanium alloy, CoCr alloys, gold alloy, zirconium dioxide.

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)

510(k) Summary K173124

PEEK Biosolution

Date of Summary: September 28, 2017

Submitter:

Company Name:	Merz Dental GmbH
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Device Name:

Proprietary name:	*PEEK Biosolution*
Common name:	Dental material
Classification reg:	21CFR 872.3690
Classification name:	Material, Tooth Shade, Resin

Predicate Devices: breCAM.BioHPP, K152113

Intended Use:

PEEK Biosolution is intended to be used for the fabrication of permanent dental restorations using CAD/CAM techniques. These are:

- Fully anatomical crowns and bridges (max. 2 pontics and min. 13 mm² connector cross-section)
- Crown copings and bridge substructures for composite veneering (max. 2 pontics and min.13 mm² connector cross-section))
- Telescopic primary and secondary crowns and frameworks
- Secondary bar structures on primary bars made of titanium alloy, CoCr alloys, gold alloy, zirconium dioxide.

Technological characteristics and substantial equivalence:

PEEK Biosolution is substantially equivalent to breCAM.BioHPP (K152113). See table below for a comparison of the two devices. Both devices are solid discs composed of polyether ether ketone (PEEK) and both are indicated for the fabrication of permanent dental restorations using CAD/CAM techniques and equipment. They only differ in dimensions.

Comparison of PEEK Biosolution to breCAM.BioHPP

Device	**PEEK Biosolution**	**breCAM.BioHPP**
Indications	Milling blank for fabrication of permanent dental restorations using CAD/CAM techniques.	Same
Intended Use	•Fully anatomical crowns and bridges •Crown copings and bridge substructures for composite veneering •Telescopic primary and secondary crowns and frameworks •Secondary bar structures on primary bars made of titanium alloy, CoCr alloys, gold alloy, zirconium dioxide.	Same
Material Class	Polyetheretherketone (PEEK)	Same
Material Form	Solid Disc with circumferential ridge	Same
Material Comp	PEEK plus pigments	Same
Disc Sizes Diameter Thickness	 95 mm 12, 16, 20, 24, 26, 30 mm	 84, 95 and 98.5 mm 12 to 25 mm
Disc Shades	White and A2/B2	Standard and Dentin
Fabrication	Milling	Same
Milling Equipment	imes-icor, Wieland Dental, Organical, Zirkonzahn or equivalent	Same
CAD/CAM Software	Software and milling equipment operated by independent dental laboratories	Same
Clearance	Subject of Application	K152113
Manufacturer	Merz Dental, GmbH	Bredent GmbH & Co.KG

PEEK Biosolution was tested and found to be in compliance with applicable dental materials standards. The results and a comparison to the predicate device, breCAM.BioHPP, are presented below.

Physical Properties of PEEK Biosolution and breCAM.BioHPP

Testing (passing value)	**PEEK BioSolution**	**breCAM BioHPP**	**PEEK Biosolution Standard**
Material	PEEK	PEEK	NA
Shape	Disc	Disc	NA
Melting temperature	339 °C	appr. 340 °C	ISO 11357
Water sorption	< 7.6 µg / mm³	6.5 µg / mm³	ISO 62
Bond strength to veneering resins after thermo cycling, (≥ 15MPa)	22 Mpa	21.4 MPa	ISO 10477
Density	1.49 ± 0.03	1.4425 g/cm³	ISO 1183
Modulus of elasticity	5100 ± 210 MPa	4550 - 4620 MPa	ISO 20795-1
Flexural strength, (>150 MPa)	178 ± 4 MPa	174 - 182 MPa	ISO 10477
Flexural strength after thermocycling, (>150MPa)	171 ± 5 MPa	173 - 174 MPa	ISO 10477
Elongation at fracture, (no fracture)	no fracture	no fracture	ISO 10477
Fracture load 3-unit bridge, > 800 N	> 910 N (limit of testing device)	1307 N	ISO 10477
Elongation at fracture, load > 7%, no fracture	no fracture	no fracture	ISO 10477

PEEK raw material (granules) used in the production of rod stock was tested by the manufacturer according to ISO 10993-1 and USP Class VI and found to be biocompatible. *PEEK Biosolution,* which is manufactured from the rod stock, was tested and found to not release extractable inorganic or organic substances, and was not cytotoxic. All tests were performed according to GLP requirements.

Summary:

Based on the above description of the Merz Dental GmbH *PEEK Biosolution* and the predicate device, Merz Dental considers *PEEK Biosolution* to be substantially equivalent to the cited predicate device, and safe and effective for its intended use.