DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 21, 2016

Bredent Gmbh & Co.KG
Stefanie Bochtler
Head Of Approvals And Regulatory Affairs
Weissenhorner Strasse 2
Senden, DE 89250 Bayern

Re: K152113
Trade/Device Name: BioHPP - breCAM.BioHPP
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: June 2, 2016
Received: June 8, 2016

Dear Stefanie Bochtler:

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Michael J. Ryan -S

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

Enclosure

bredent

Indications for Use Statement

510(k) Number: **K152113**

Device Name: BioHPP

Indications for Use:

BioHPP polymer is used for the fabrication of definitive crown and bridge frameworks with no more than 2 pontics and for definitive removable restorations. BioHPP can also be used for fully anatomical pressed bridge structures - with or without buccal composite veneering.

- Fully anatomical crowns and bridges (max. 2 pontics)
- Crown copings and bridge substructures for composite veneers (max. 2 pontics)
- 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 _____
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use Statement

510(k) Number: **K**_____

Device Name: breCAM.BioHPP

Indications for Use:

breCAM.BioHPP is used for the fabrication of permanent restorations using CAD/CAM techniques.

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. Reference is made to the instructions for use "BioHPP elegance prefab for SKY" to fabricate an individual abutment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K_____

VOLUME 006

510(k) Summary

DATE OF APPLICATION: 2015-07-17

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1. Device Name

Trade Names: BioHPP - breCAM.BioHPP
Common Name: Dental material
Classification Name: material, tooth shade, resin.

2. Classification Product Code / Subsequent Code

Bredent BioHPP and breCAM.BioHPP can be classified according to following FDA Device Name and Product Code:

	Device	Regulation Medical Speciality / Review Panel	Product Code	Device Class	Regulation Description	Regulation Number
Predicate	Material, Tooth Shade, Resin	Dental	EBF	2	Tooth shade resin material.	872.3690

3. Predicate Device

Bredent BioHPP and breCAM.BioHPP are substantially equivalent to the following predicate devices, already cleared by the FDA:

Predicate Device	510(k) Number	510(k) Holder
TRINIA	K133608	BICON, LLC 501 Arborway Boston, MA 02130
Juvora PEEK	K132725	JUVORA Technology Centre Hillhouse International Thornton-cleveleys, Lancashire, GB fy5 4qd

4. Description of the Device

4.1. BioHPP

BioHPP is a tooth-colored thermoplastic high-performance polymer based on polyether ether ketone (PEEK), which was developed especially for the fabrication of dental restorations. Bio HPP is available in two different variations - as a granular material and prefabricated cylinders with diameters of 15 mm and 25 mm (so-called pellets). The two different pellets have a weight of 4 g (diameter: 15 mm) and 15 g (diameter: 25 mm). The small pellets with a diameter of 15 mm can be used in the smaller mold with a diameter of the press plunger of 16 mm. The large pellets with a diameter of 25 mm are intended exclusively for processing in the large mold with a press plunger diameter of 26 mm. In addition to high biocompatibility, BioHPP material features high mechanical, thermal and chemical resistance. BioHPP is melted in a standard preheating furnace at 400° C and pressed into an investment ring in the for 2 press vacuum press device, which is required for this application.

Overview of capacities:

BioHPP Type of material	Base former, size 3, with a diameter of 16 mm	Base former, size 9, with a diameter of 20 mm	Base former, size 9, with a diameter of 26 mm and metal ring
Granular material	max. 4,6 g	max. 8,7 g	max. 15 g
Pellet 15 mm (4 g each)	1 pellet	2 pellets	3 pellets
Pellet 25 mm (15 g each)	not possible	not possible	1 pellet

4.2. breCAM.BioHPP

breCAM.BioHPP is based on filled polyether ether ketone (PEEK) and used for the fabrication of permanent crowns and bridges using CAD/CAM techniques. Three sizes are available.

54002029 breCAM.BioHPP Ø 98,5 x 12 mm
54002030 breCAM.BioHPP Ø 98,5 x 16 mm
54002031 breCAM.BioHPP Ø 98,5 x 20 mm
54002032 breCAM.BioHPP Ø 98,5 x 24 mm

54002089 breCAM.BioHPP Ø 95 x 12 mm ZZ
54002091 breCAM.BioHPP Ø 95 x 20 mm ZZ
54002092 breCAM.BioHPP Ø 95 x 25 mm ZZ
54002111 breCAM.BioHPP Ø 84,5 x 20 mm AG

breCAM.BioHPP dentin-shade 2

54002069 breCAM.BioHPP dentin-shade 2 Ø 98,5 x 12 mm
54002070 breCAM.BioHPP dentin-shade 2 Ø 98,5 x 16 mm
54002071 breCAM.BioHPP dentin-shade 2 Ø 98,5 x 20 mm
54002072 breCAM.BioHPP dentin-shade 2 Ø 98,5 x 24 mm

54002099 breCAM.BioHPP dentin-shade 2 Ø 95 x 12 mm ZZ
54002101 breCAM.BioHPP dentin-shade 2 Ø 95 x 20 mm ZZ
54002102 breCAM.BioHPP dentin-shade 2 Ø 95 x 25 mm ZZ
54002121 breCAM.BioHPP dentin-shade 2 Ø 84,5 x 20 mm AG

5. Indications for Use

5.1. BioHPP

BioHPP high-performance polymer is used for the fabrication of definitive crown and bridge frameworks with no more than 2 pontics and for definitive removable restorations. BioHPP can also be used for fully anatomical pressed bridge structures - with or without buccal composite veneering.

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

5.2. breCAM.BioHPP

breCAM.BioHPP is used for the fabrication of permanent restorations using CAD/CAM techniques.

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. Reference is made to the instructions for use “BioHPP elegance prefab for SKY” to fabricate an individual abutment.

6. Technological Characteristics

	NEW DEVICE	**NEW DEVICE**	**PREDICATE DEVICE 1**		**PREDICATE DEVICE 2**	
510(k) Submitter/ Holder	**Bredent**		**Bicon LLC**		**Juvora**	
Trade Name	**BioHPP**	**breCAM.BioHPP**	**TRINIA**		**Juvora PEEK**	
510(k) Number	-		K133608		K132725	
Material	PEEK		Glass fiber Modified epoxy resin		PEEK-OPTIMA LT1	
Shape	Granulate – Pellets	Disc	Disc		Disc	
Melting temperature/range < 500 °C	Approx. 340°C		-	-	Melt Temperature	340°C

	NEW DEVICE	NEW DEVICE	PREDICATE DEVICE 1		PREDICATE DEVICE 2	
510(k) Submitter/ Holder	**Bredent**		**Bicon LLC**		**Juvora**	
Trade Name	**BioHPP**	**breCAM.BioHPP**	**TRINIA**		**Juvora PEEK**	
Water absorption ≤ 40 µg/mm3	6.5 µg/mm3		Water absorption	0.03%	24-Hour Water Absorption	0.5%
Water solubility ≤ 7,5 µg/mm3	0,1 µg/mm3		-	-	-	-
Bond strength to veneering resins ≥ 15 MPa	25.2 MPa		Shear bond Strength to Enamel	18 MPa	-	-
Bond strength to veneering resins after thermocycling ≥ 15 MPa	21.4 MPa		Shear Bond Strength to Dentin	10 MPa	-	-
Surface roughness after polishing (SA) [µm]	0.057 µm		-	-	-	-
Density [g/cm3]	1.4425 g/cm^3		Density / Specific gravity	1.68 g/cm^3	Density (g/cm^3)	1.29 g/cm^3
Modulus of elasticity 3.800 – 5000 MPa	4083 ÷ 4630 MPa	4550÷4620 MPa	Flexural modulus of elasticity	18.8 GPa	Flexural modulus	4 GPa
Modulus of elasticity after thermocycling 3800 – 5000 MPa	3970 ÷ 4640 MPa	4610÷4780 MPa	Tensile modulus of elasticity	18.8 GPa	-	-
Flexural strength >150 MPa	163 ÷ 179 MPa	174 ÷ 182 MPa	Flexural strength	393MPa	-	-

	NEW DEVICE	NEW DEVICE	PREDICATE DEVICE 1		PREDICATE DEVICE 2	
510(k) Submitter/ Holder	**Bredent**		**Bicon LLC**		**Juvora**	
Trade Name	**BioHPP**	**breCAM.BioHPP**	**TRINIA**		**Juvora PEEK**	
Flexural strength after thermocycling >150 MPa	157 ÷ 171MPa	173 ÷ 174 MPa	-	-	-	-
Elongation at fracture >6.5%, no fracture	>7% ÷ >9% no fracture	>8% ÷ >9% no fracture	Flexural strain at max stress	2.7 %	-	-
Elongation at fracture after thermocycling >6.5%, no fracture	>7% ÷ >9% no fracture	>7% ÷ >9% no fracture	-	-	-	-
Fracture load 3-unit bridge >800 N	1307 N	1387 N	-	-	-	-
Elongation at fracture from fracture load >7%, no fracture	No fracture	No fracture	-	-	-	-
Fracture load after mechanical and thermal load cycles >800 N	1500 N	-	-	-	-	-

7. Testing

To evaluate the physical properties of BioHPP and breCAM.BioHPP tests according DIN EN ISO 10477 (ISO 10477:2004) have been performed.

8. Biocompatibility

All requirements of biocompatibility are met through the composition of the used materials which demonstrate the appropriate levels of biocompatibility for its intended use. The used materials are also used in many other medical devices and have an established history of use and biocompatibility. Performed testing provides evidence on acceptable levels of biocompatibility.

Compared with competitor devices, Bredent BioHPP and breCAM.BioHPP are made out of substantially equivalent or identical materials.

9. Substantial Equivalence Summary / Conclusion

Based on available 510(k) information provided herein, BioHPP and breCAM.BioHPP are considered substantial equivalent to the predicate devices in terms of indications for use, material, technology, design and performance specifications.