CENDRES+METAUX SA
Uli DIERMANN
Head of Regulatory Affairs
Rue De Boujean 122
CH-2501 Biel/Bienne
Switzerland

November 13, 2017

Re: K170102
Trade/Device Name: Pekkton Ivory
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, POW
Dated: September 21, 2017
Received: September 27, 2017

Dear Uli DIERMANN:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170102

Device Name

Pekkton® Ivory

Indications for Use *(Describe)*

- Definitive supported and veneered crowns and bridges with maximum two pontics. Can be veneered with bonded press crowns, with composites or prefabricated acrylic teeth and veneers.
- Definitive supported, veneered single crowns and bridges with maximum one pontic on natural teeth.
- Removable restoration such as secondary structures on bars and telescopic crowns, transversal connectors, occlusal splints and denture bases.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary: Pekkton® Ivory (K170102)

510(k) Owner	:	CENDRES+METAUX SA Rue de Boujean 122 CH-2501 Biel / Bienne Phone : +41 58 360 20 00 Fax : +41 58 360 20 10
Contact person	:	Uli Diermann (uli.diermann@cmsa.ch)
Date of Preparation	:	09 November 2017
Trade Name	:	Pekkton® Ivory
Common Name	:	dental material, milling blank, press blank
Classification Name:	:	Tooth shade resin material
Classification	:	Class II
Product Code	:	EBF
Regulation Number	:	872.3690

Primary predicate device, legally marketed device to which substantially equivalence is claimed

Primary predicate device	510(k) Number	510(k) Holder
BioHPP- breCAM.BioHPP	K152113	Bredent Gmbh & Co.KG
Reference device	510(k) Number	510(k) Holder
Pekkton® Ivory	K123638	CENDRES+METAUX SA

Description of the device

Pekkton® Ivory is a semi-crystalline thermoplastic supplied in milling blanks and press blanks. By application of CAD/CAM milling or pressing technology according to the instructions for use, it can be used by the dental technician to manufacture permanent crowns, bridges and denture frameworks.

Indication for Use of the device

- Definitive supported and veneered crowns and bridges with maximum two pontics. Can be veneered with bonded press crowns, with composites or prefabricated acrylic teeth and veneers.
- Definitive supported, veneered single crowns and bridges with maximum one pontic on natural teeth.
- Removable restoration such as secondary structures on bars and telescopic crowns, transversal connectors, occlusal splints and denture bases.

Summary Technological Characteristics

The proposed Pekkton® Ivory is substantially equivalent to the predicate device. The difference between Pekkton® Ivory and the predicate device BioHPP is not significant. Any differences do not affect the safety and effectiveness of the device when used as labeled.

Substantial equivalence comparison to the predicate device

		Predicate Device		**Candidate**	**Remarks**
Device Name	:	**BioHPP- breCAM.BioHPP**		**Pekkton® Ivory**	
510(k) No	:	K152113		K170102	
Classification Name	:	Tooth shade resin material		Tooth shade resin material	Same classification name
Product Code	:	EBF		EBF	Same code
Regulation Number	:	872.3690		872.3690	Same regulation
Intended Use	:	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.		Pekkton® Ivory is intended for use with fixed (crowns and bridges) and removable dental prostheses.	Comparable intended use
Indications for use	:	BioHPP	breCAM.BioHPP	Pekkton® Ivory	
		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.	breCAM.BioHPP is used for the fabrication of permanent restorations using CAD/CAM techniques.	Definitive supported, veneered and screw-retained crowns and bridges on dental implants, with maximum two pontics. Can be veneered with bonded press crowns, with composites or prefabricated acrylic teeth and veneers.	In general the indications are comparable, but the wording is different. The Pekkton® indications focus on the application for maximum 2 pontics. But bridge structures and buccal composite veneering is covered in the indications. The indications of BioHPP do not differentiate between natural teeth and implants. For Pekkton® the indication differentiate between both. Pekkton® is indicated only for removable restorations. It an be can be used for all standard materials The differences do not have impact on safety and effectiveness of the device Pekkton® Ivory.
		Crown copings and bridge substructures for composite veneers (max. 2 pontics)	Crown copings and bridge substructures for composite veneering (max. 2 pontics and min.13 mm² connector cross-section))	Definitive supported, veneered single crowns and bridges with maximum one pontic on natural teeth.	
		Fully anatomical crowns and bridges (max. 2 pontics)	Fully anatomical crowns and bridges (max. 2 pontics and min. 13 mm² connector crosssection)		
		Telescopic primary and secondary crowns and frameworks		Removable restorations such as secondary constructions on bars and telescopic crowns, transversal connectors, occlusal splints and denture bases.	
		Secondary bar structures on primary bars made of titanium alloy, CoCr alloys, gold alloy, zirconium dioxide			

	Predicate Device		Candidate		Remarks
	BioHPP- breCAM.BioHPP		**Pekkton® Ivory**		
Material :	PEEK (Plyetheretherketone)		PEKK (Polyetherketoneketone)Titanium Dioxide		PEEK and PEKK belong both to the family of poly-aryl-ether-ketones (PAEK).
Form :	Granulate-Pellets	Disc	Press blanks	Milling blanks	Comparable forms
Processing :	Melt processing of thermoplastic (Heat and pressure)	CAD/CAM Milling	Melt processing of thermoplastic (Heat and pressure)	CAD/CAM Milling	Comparable processing
Melting temperature :	approx. 340°C		Approx. 363 °C		Comparable temperature
Bond strength to veneering resins :	25.2 MPa		> 15 MPa		Standard ISO EN 10477:2004 requires 5 MPa
E-Modulus :	approx. 4083 – 4630 MPa		approx. 5000 MPa		ASTM-D638
Flexural strength :	163 – 179 MPa		200 MPa		ASTM-D790
Water absorption :	6.5 ug/mm3		8.7 ug/mm3		Standard ISO 4049-2009 requires water sorption lower than 40 ug/mm3
Water solubility :	0.1 ug/mm3		0.2 ug/mm3		Standard ISO 4049-2009 requires water solubility lower than 7.5 ug/mm3

Table 5-1

We conclude that for all significant parameters Pekkton® Ivory is substantially equivalent to its above mentioned predicate device BioHPP- breCAM.BioHPP.

Summary of Testing to Demonstrate Substantial Equivalence / Conclusion:
For the risk assessment of biological risks, the procedures and provisions of ISO 10993-1:2009 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process", recognition number 2-156, were applied. Based upon the criteria set out in this standard, the product is biologically classified as an "external communicating device" with "permanent" (> 30 days) contact to "tissue, bone or dentine".

In accordance with the aforementioned standards, in accordance with ISO 7405:2008 Dentistry - evaluation of biocompatibility of medical devices used in dentistry including: amendment 1 (2013), recognition number 4-212 and in accordance with "510(k) Memorandum - #G95-1 Attachment B – Table 2 Supplementary Evaluation Tests for Consideration", the following test methods were particularly considered, conducted and passed the criteria:

Test methods	Standard	Recognition Number
Cytotoxicity	ISO 10993-5:2009	2-153
Irritation	ISO 10993-10:2010	2-174
Delayed-type hypersensitivity	ISO 10993-10:2010	2-174
Systemic Toxicity	ISO 10993-11:2006	2-176
Subchronic and chronic systemic toxicity	ISO 10993-11:2006	2-176
Implantation	ISO 10993-6:2007	2-177
Genotoxicity	ISO 10993-3:2014	2-228
Chemical characterization	ISO 10993-18:2009	-
USP Plastic Class VI	USP 34 (88)	-

Table 5-2

The subject device Pekkton® Ivory (K170102) is identical to the reference device Pekkton® Ivory (K123638). No incidents or adverse events have been reported since the market launch of Pekkton® Ivory (K123638).
Non-clinical test data was used to support the substantially equivalence claim. Non-clinical testing consisted of analysis of devices to identify worst-case test samples. The evaluation was based on FDA guidance "Guidance for Industry and FDA Staff, Dental Composite Resin Devices – Premarket Notification (510(k)) Submissions."
Chemical-, physical properties, and bond strength to veneering composites have been evaluated. Static fracture load and fatigue tests as well as simulated use tests have been conducted to evaluate the performance characteristics of Pekkton® Ivory. The test methods were based on established standards and guidelines. Testing has shown that Pekkton® Ivory is equivalent in performance characteristics to the predicate device BioHPP. The acceptance criteria were met.

The summary of application and functional testing indicate that the device is substantially equivalent to the predicate device.