Zirkonzahn Srl
% Mark Job
Official Correspondent
Regulatory Technology Services, LLC
1394 25th Street, Nw
Buffalo, Minnesota 55313

June 18,2018

Re: K181484
Trade/Device Name: Tecno Med, Tecno Med Mineral, Tecno Med Mineral Dentine, Tecno Med Mineral Tissue
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: June 1, 2018
Received: June 5, 2018

Dear Mark Job:

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 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

forTina 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181484

Device Name
Tecno Med, Tecno Med Mineral, Tecno Med Mineral Dentine, Tecno Med Mineral Tissue

Indications for Use *(Describe)*

TECNO MED MINERAL, TECNO MED MINERAL DENTINE and TECNO MED MINERAL TISSUE are used to create reduced crowns and bridges (max. 2 pontics and min. 13 mm² connection cross-section), telescopic primary crowns, copings as well as frameworks for composite veneered bridges. The width of the bridge must not exceed two pontics for reasons of stability.
TECNO MED is designed for the manufacturing of frictional elements on telescopic restorations or attachments.

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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5. 510(k) Summary K181484

Date of summary: 2018-05-18

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Device Name

Proprietary Name: Tecno Med, Tecno Med Mineral, Tecno Med Mineral Dentine, Tecno Med Mineral Tissue

Common Name: Dental Polymer Discs

Classification

Review Panel: Dental
Device Class: II
Product Code: EBF
Subsequent Product Code: EBI
Classification Name: material, tooth shade, resin
Regulation Number: 872.3690

Predicate Device

Already cleared device selected to demonstrate substantial equivalence:
Company: Bredent GmbH & Co. KG
Predicate Device Name: breCAM.BioHPP
510(k) Number: K152113
Product Code: EBF
Subsequent Product Code: EBI
Class: II

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Device Description

Tecno Med and the three Tecno Med Mineral devices are tooth-shade polymer discs based on polyether ether ketone (PEEK). These discs are available in a variety of shapes for different milling systems. For each device, there are two diameter variants, 95 mm and 98 mm. The discs with a diameter of 98 mm are additionally available with or without step. Moreover, each model is provided in different heights (8mm-30 mm). The users can choose according to their requirements and preferences among the different models. Tecno Med Mineral, Tecno Med Mineral Dentine as well as Tecno Med Mineral Tissue have the same indications for use, for the Tecno Med device there are other indications for use.

These polymer discs are used by specifically trained personnel using CAD/CAM techniques.

Indications for use

TECNO MED is designed for the manufacturing of frictional elements on telescopic restorations or attachments.

TECNO MED MINERAL, TECNO MED MINERAL DENTINE and TECNO MED MINERAL TISSUE are used to create reduced crowns and bridges (max. 2 pontics and 13 mm² connection cross-section), telescopic primary crowns, copings as well as frameworks for composite veneered bridges. The width of the bridge must not exceed two pontics for reasons of stability.

Technological Characteristics and substantial equivalence

Chemical composition:

The new devices as well as the predicate devices are based on PEEK, therefore they are similar in their chemical composition.

Indications for use:

The indications for use of the new and predicate devices are similar.

Intended user:

The subject devices as well as the predicate devices are intended to be further processed by specifically trained personnel.

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Non-clinical performance:

Non clinical testing was performed to determine the physical properties of the subject devices. In consideration of the International Standard ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing, the subject devices were tested to evaluate: In-vitro cytotoxicity, Skin sensitization, Irritation, Mutagenicity. Biocompatibility testing demonstrated that no issue of biocompatibility arises. Furthermore, on the subject devices testing according to ISO 10477:2004 and DIN EN ISO 20795-2:2013 were performed. All test samples meet the requirements set by the standards.

The results of nonclinical tests demonstrate that the devices are equivalent to the predicate device.

	NEW DEVICES				**PREDICATE DEVICE**
Trade Name	Tecno Med Mineral	Tecno Med Mineral Dentine	Tecno Med Mineral Tissue	Tecno Med	breCAM.BioHPP
Shades	White	Dentine	Tissue	Natural	White & Dentine
Melting Temperature	Approx. 340 °C				Approx. 340 °C
Water absorption (according to 10477:2004	7.3 µg/mm³	6.5 µg/mm³	7.2 µg/mm³	4.73 µg/mm³	6.5 µg/mm³
Water solubility (according to 10477:2004)	1.2 µg/mm³	0.6 µg/mm³	1.2 µg/mm³	1.67 µg/mm³	0.1 µg/mm³
Density	1.49 g/cm³	1.52 g/cm³	1.36 g/cm³	1.31 g/cm³	1.44 g/cm³
Modulus of elasticity	4100 MPa	4400 MPa	5100 MPa	≥ 4300 MPa	4585 MPa
Flexural strength (according to 10477:2004)	201 MPa	198 MPa	189 MPa	174 MPa	178 MPa
Biocompatibility (according to ISO 10993)	Established				Established

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The Zirkonzahn devices as well as the breCAM.BioHPP device are available as milling blanks. These blanks can be obtained in different shapes for different milling systems, different heights and different dental shades. Zirkonzahn provides a broader range of color shades as Bredent. This difference results from the fact that Zirkonzahn wants to provide to the customer a broader range of options. The specifically trained staff may choose among them, according to the aesthetic requirements.

The subject device and the predicate device meet the requirements of the applicable ISO standards and show similar results.
The test data shown above indicate that the subject devices are substantially equivalent to the predicate device.

Conclusion

The new devices of Zirkonzahn srl are substantially equivalent to the cleared predicate device as they are similar in their indications for use, material, technology, design and performance specifications.