April 24, 2020

Bioden Co., Ltd
% Chris Park
General Manager
Med.com
1809 Holland Dr
Somerset, New Jersey 08873

Re: K190139
Trade/Device Name: Zircos-Com
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: January 22, 2020
Received: January 28, 2020

Dear Chris Park:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K190139

Device Name
Trade Name: Dental Composites and Filling Materials
Common Name: Dental Composites and Filling Materials
Trade name: Zircos-Com

Indications for Use *(Describe)*
- Direct fillings of Class I to V restorations
- Shape and shade corrections

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92

The assigned 510(k) Number: K190139

1. Date of Preparation: 08, April, 2020

2. Sponsor Identification

BIODEN Co.,Ltd
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3. Identification of Proposed Device

Trade Name: Dental Composites and Filling Materials
Common Name: Dental Composites and Filling Materials
Trade name: Zircos-Com

Regulatory Information

Classification Name: Tooth Shade Resin
Classification: 2

Product Code: Class II Device / EBF (21 CFR 872.3690) Review Panel: Dental
Indication for use Statement:

- Direct fillings of Class I to V restorations
- Shape and shade corrections

Device Description

Zircos-com is light-cured, radiopaque hybride composite resin. Zircos-Com is hybride composite resin for anterior and posterior restorations. Zircos-Com is reinforced filler composite.

4. Identification of Predicate Device(s)

Predicate Device

- 510(k) number: K102351
- Name: Dental Composites and Filling Materials
- Model: Grandio SO
- Company: VOCO GmbH
- Classification: 2

5. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device, including

- Cytotoxicity per ISO 10993-5:2009;
- Intracutaneous Reactivity Test per ISO 10993-10:2010;
- Sensitization Test per ISO 10993-10:2010
- Acute Systematic Toxicity per ISO 10993-11:2006;
- Genotoxicity Tests per ISO 10993-3:2014.

6. Clinical Test Conclusion

No clinical study is included in this submission.

7. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

1. Bioden Co., Ltd Zircos-com VS Dentsply sirona's AH plus					
No	Division		Bioden CO., Ltd	VOCO GmBH	Substantial Equivalence Discussion
			Zircos-Com	Grandio	
1	Clinical	Indication for Use	Zircos-Com is used for -Direct fillings of Class I to V restorations -Shape and shade corrections	Grandlo SO is intended for use as: - class I to V fillings - reconstruction of traumatically affected anteriors - facetting of discolored anteriors - correction of shape and shade for improved aesthetic appearance - locking, splinting of loose anteriors - repairing veneers - restoration of deciduous teeth - core-build-up under crowns - composite inlays	Similar with predicate
2		Intended target groups	Patients who are men of all ages and sexes and need tooth root canal treatment patient, patient who cementing restorations or cementing temporary crowns and bridges.	Patients who are men of all ages and sexes and need tooth root canal treatment patient, patient who cementing restorations or cementing temporary crowns and bridges.	Equivalence

3	Technical	Structure			Equivalence
4		CE Marking		CE 0482	Similar Equivalent products and performance are not identical, but all are tested according to ISO 3107 and passed the reference value. Also, it was confirmed that the result of checking the sales history shows no adverse effect in any performance problem.
5		Curing type	Light-curing type	Light-curing type	
6		Curing time	20-40sec	20-40sec	
7		Composition	Zircos-Com consists of a paste system, which is delivered in self-manufactured high viscosity black syringe.	Grandio consists of a paste system, which is delivered in high viscosity black syringe.	Equivalence
8	Technical	Using method &procedure	1. Shade selection Clean tooth with pumice and water to remove surface stains or extraneous plaque. Prior to isolation of tooth, select the appropriate shade. (We are recomend the Vita shade guide) 2. Cavity preparation Remove all amalgam or other base materials that interfere with operations. 3. Pulp protection In deep cavities cover the dentin close to the pulp with a minimum amount of calcium hydroxide liner leaving the rest of cavity surface	1. Preparation / Shade selection Clean the teeth to be treated with a fluoride-free cleaning paste. Mark occlusal contact points(Posterior area); a minimal seperation facilitates the design of the approximal contact and placing of the matrix. Before anaesthesia, moisten the Grandio shade guide and match the shade to the moist, clean tooth in daylight 2. Drying Ensure that the working field is dry. Using a rubber dam is recommended.	Equivalence

			free bonding. Glass ionomer or other eugenol-free materials may be used, if wished. 4. Enamel and dentin treatment Follow the manufacturer's instructions regarding etching, priming, adhesive application and curing. 5. Place composite Allow Zircos-Com to reach room temperature before application. For cavities in approximal areas apply a matrix. Using a translucent matrix is beneficial.(smooth surfaces) Apply the desired shade of Zircos-Com and adapt it to the cavity with a suitable instrument. For fillings of more than 2mm, 2mm apply and polymerize in layers. Insert caps into the opening of the dispenser following the respective instructions for use. Turn caps in the desiresed direction and remove the protective cover. Apply Zircos-Com directly into the cavity by slowly and evenly pressing the levers of the handle together. 6. Curing Expose each area of restoration surface to a high intensity visible light source. Hold the light guide tip as close to the restorative as possible during exposure. Light cure for 20~40 seconds with a standard light curing unit. (If light curing unit output is below 1,200mW/㎠, as measured by a curing radiometer, more time may be needed.) 7. Finishing Finish and polish using conventional techniques.	3. Cavity preparation Generally, cavity preparation should be carried out according to the rules of the adhesive filliing therapy, i.e. minimally invasive to conserve healthy tooth substance. Bevel the enamel margins on anteriors and round off the preparation margins on posteriors. Non-carious cervical lesions do not have to be prepared; thorough cleaning sufficient here. Afterwards, clean and dry the cavity. 4. Lining A Calcium hydroxide lining should be applied in proximity of the pulp. Place a layer of stable cement over the lining. Due to their fluoride release, glass polyalkenoate(Glass ionomer) materials are recommended. 5. Bond material Grandio is used in adhesive technique with a dentin/enamel bond. All light-curing bonding materials may be used. Follow the respective instructions for use with regards to preparation (etch technique) and application 6. Application of Grandio Let the material reach room temperature before application. Place a matrix on cavities in the approximal area. Using translucent matrice is advantageous(smooth surfaces). Apply the chosen shade of Grandio (See shade selection) and adapt it with a suitable instrument. Apply and polymerize fillings of more than 2mm in layers. 7. Light-curing Conventional polymerization devices are suited for light-curing this material. The light output should be a minimum of 500mw/cm2 on halogen polymerization devices and 300mw/cm2 on LED devices. The curing time	

				is a minimum of 20 sec per layer, for opaque shade OA2 and OA3.5, a minimun of 40sec. Hold the light emission tip of the device as close as possible to the surface of the filling. If the distance is more than 5mm, the curing depth may be compromised. Incomplete curing may lead to discoloration and pulpitiis-like complaints. 8. Finishing The filling can be finished and polished immediately after removing the shaping aids(e.g. fine or extra fine diamond burst, polishing disc), with cooling provided. The margin of the filling or the entire tooth should be fluoridated as a final step. Grandio can be used for direct and indirect and indirect inlays according to customary methods. The physical stability can be improved by the usual external(additional) Curing.	
			1. Do not store at high temperature or intense light. 2. Keep in a cool place.(1~30℃)	Strore at temporarytures between 4℃~ 23℃. If refrigerated, the material must be allowed to reach room temperature before use. To avoid exposure to light and possible polymerization, syringes should be closed immidiately after dispensing. Do not use Grandio after the expiry date.	Equivalence
9	Technical	Caution	1. Zircos-Com must be handled by dentists and dental specialists according to the instructions before using it. 2. Recommend the Rubber dam for reduction of reaction for use with patients who have a history of severe allergic reaction to material. 3. Do not use to patients who have rash on their skin, dermatitis or histories of hypersensitivity. 4. Stop applying this material to the patients who have symptoms of	- No known side effects. Hypersensitive persons may develop sensitivities. - Phenolic substances, especially eugenol-orthymol-containing preparations interfere with curing filling composites. The use of zinc oxide eugenol cements or other eugenol-containing materials in combination with filling composites should be avoided. - Filling exposed to occlusal forces should be checked at least once a year for early detection of changes.	Equivalence

			hypersensitivity during using. 5. This material is used only to the oral tissue. Avoid contact with eyes. 6. If accidental contact occurs with eyes or skin, wash immediately with much water and seek medical advice. 7. Non-specialists must not use this material. Do not use this material for other purposes. 8. Protective device for the respiratory tract is highly recommended before a surgical operation. 9. Do not use after expiration date. (within 3 years) 10. The product is dissolved in alcohol when uncured or so can cause allergic reactions, applies a su_cient curing time according to the usage. 11. After curing light according to the instruction, remove the uncured materials and wipe surface with gauze again.		
10	Biological equivalence	Biocompatibility assessed	All fluid contact parts are ISO 4049 compliant.	All fluid contact parts are ISO 4049 compliant.	Equivalence
		Side-effect	There is no side-effect	There is no side-effect	Reference to the above section 2.5 from MHRA
Conclusion			The Bioden's Zircos-Com and the VOCO GmBH's Grandio are equivalence to each other in terms of Clinical, technical and biological characteristics following above chart. In aspect of clinical part, they all both are used for the same clinical condition, used for the same intended purpose, and used at the same site in the body. In aspect of technical part, they all both are used under the same conditions of use, and have similar specifications and properties and have similar principles of operation and critical performance requirements. In aspect of biological part, they all both use the same materials or substances in contact with the same human tissues.		

Subject device, Based on the table above, the intended use of Zircos-Com is identical to the other equivalent devices and there is no significant clinical difference in the performance and stability when comparing the technical characteristics and biological natures.

Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.