March 10, 2021

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

Re: K201492
Trade/Device Name: Non-Sterile Zirconia Block
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: December 3, 2020
Received: December 10, 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,

Michael E. Adjodha, M.ChE.
Assistant 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)*
K201492

Device Name
Non-Sterile Zirconia Block
Model: name: Zircos-E ACE

Indications for Use *(Describe)*
Non-Sterile Zirconia Block (Model: Zircos-E ACE) is indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.

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: **K201492**

1. Date of Preparation: Mar/09/2021

2. Sponsor Identification

BIODEN Co.,Ltd
Address: #B-803 119, Gasan digital 1-ro, Geumcheon-gu, Korea
Establishment Registration Number: Not yet registered for the Number
Contact Person: MyeongEun Song
Position: QA
Tel: +82-2-6292-2840
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3. Identification of Proposed Device
Trade Name: Non-Sterile Zirconia Block
Common Name: Zirconia Blocks

Regulatory Information

Classification Name: Porcelain powder for clinical use
Classification: 2

Product Code: EIH Regulation Number: 872.6660 Review Panel: Dental
Indications for Use Statemen:
Non-Sterile Zirconia Block (Model name: Zircos-E ACE) is indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.

Device Description
Non-Sterile Zirconia Block (Model name: Zircos-E ACE) is a manufacture unit that is cut, processed and sintered by CAD/CAM system of the computers designed for production of dental restoration.

4. Identification of Predicate Device(s)

Primary predicate

- 510(k) number: K190112
- Company: FINE ADVANCED COMPOUND Co., Ltd
- Model: Finebase, Montblanc, Trione HT, Trione C, Trione HT+
- Classification: Class II

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

- Performance Test per ISO 6872 Fourth Edition 2015-06-01, Dentistry - Ceramic Materials.
- Density Test
- 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;

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6. Clinical Test Conclusion

No clinical study is included in this submission.

7. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Non-Sterile Zirconia Block (Model name: Zircos-E ACE)	Non-Sterile Zirconia Block (Model name: Finebase, Montblanc, Trione HT, Trione C, Trione HT+)	Model names various
Product Code	EIH	EIH	Equivalen
Regulation Number	872.6660	872.6660	ceEquivalence
Indication for use	Non-Sterile Zirconia Block (Model name: Zircos-E ACE) are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.	Non-Sterile Zirconia Block (Model name: Finebase, Montblanc, Trione HT, Trione C, Trione HT+) are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.	Indication for use is equal
Feature	Colored	Colored	Equivalencel
Shape	Discs	Discs	Equivalence
Type and Class per ISO 6872: 2015	Type II Class 5	Type II Class 5	Equivalence
Sterility	Non-sterile	Non-sterile	Equivalence
Chemical Composition	ZrO2 with others	ZrO2 with others	Equivalencel
Crystal Morphology	Tetragonal	Tetragonal	Equivalence
Density	6.00g/cm^3	6.00g/cm^3	Equivalence
Sintering temperature	1500±50℃	1500±50℃	Equivalence
Performance	Comply with ISO 6872	Comply with ISO 6872	Equivalence
Contact Level	surface device with permanent contact	surface device with permanent contact	Equivalence
Biocompatibility	Tested for Cytotoxicity, irritation, sensitization, accurate systematic toxicity, genotoxicity, no adverse react	Tested for Cytotoxicity, irritation, sensitization, accurate systematic toxicity, genotoxicity, no adverse react	Equivalence

Subject device, Based on the table above, the intended use of Zircos-E ACE 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.

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Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices Non-Sterile Zirconia Block (Model name: Zircos-E ACE) is determined to be Substantially Equivalent (SE) to the predicate devices K190112/ Company: FINE ADVANCED COMPOUND Co., Ltd/ Model: Finebase, Montblanc, Trione HT, Trione C, Trione HT+.