March 05, 2020

Meta Biomed Co., Ltd.
℅ April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

Re: K191991
Trade/Device Name: Ezfil
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: December 2, 2019
Received: December 6, 2019

Dear April Lee:

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 Srivinas ‘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)*
K191991

Device Name
Ezfil

Indications for Use *(Describe)*
- Direct anterior and posterior restorations (including occlusal surfaces)
- Core Build-ups
- Splinting
- Indirect restorations including inlays, onlays 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

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Device Information

- Trade Name: Ezfil
- Classification Name: Tooth Shade Resin Material
- Product Code: EBF
- Panel: Dental
- Regulation Number: 21 CFR 872.3690
- Device Class: Class II
- Date prepared: 03/05/2020

Primary Predicate Device:

- K083610, Filtek Supreme Ultra Universal Restorative manufactured by 3M COMPANY

Device Description

Dental composite resin is a device intended to restore carious lesions or structural defects in teeth.

Ezfil is indicated for Class Ⅰ, Ⅱ, Ⅲ, Ⅳ, Ⅴ restorations, Core-buildup to replace missing tooth structure, Diastema closures, Direct veneers, Composite and porcelain repairs.

The color is 18 colors with A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, OP and TL.

Indication for Use

- Direct anterior and posterior restorations (including occlusal surfaces)
- Core Build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers

Non-clinical Testing

The following testing was conducted on our subject device:

- Biocompatibility Tests according to EN ISO 10993-1:2009, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-10:2013, ISO 10993-11:2009.
- Performance tests such as Sensitivity of ambient light, Depth of cure, Shade, Color Stability, Flexural strength, Water Sorption, Solubility and Radio-opacity according to EN ISO 4049:2009.
- Shelf Life test: ISO 4049 tests (Package, Sensitivity to Ambient Light, Depth of Cure, Shade, Colour Stability, Flexural Strength)
- Compressive Testing according to ISO 3107:2011
- Surface Hardness Testing according to ISO 6507-1:2005

Summary of Technological Characteristics:

The subject device and the primary predicate device have the same intended use and have the similar technological characteristics and are made of similar materials. They encompass the same range of physical and chemical properties. The subject device and predicate devices are packaged in similar material and use similar methods of application.

The subject device is different from the primary predicate device in raw materials, however, the test results provided in this submission supports that it is substantially equivalent to the primary predicate.

	Subject Device	Primary Predicate Device
Manufacturer	Meta Biomed Co., Ltd.	3M COMPANY
Device Name	Ezfil	Filtek Supreme Ultra Universal Restorative
510(k) Number	K191991	K083610
Classification Name	Tooth shade resin material	Tooth shade resin material
Product Code	EBF	EBF
Regulation Number	21 CFR 872.3690	21 CFR 872.3690
Indications for use	● Direct anterior and posterior restorations (including occlusal surfaces) ● Core Build-ups ● Splinting ● Indirect restorations including inlays, onlays and veneers	● Direct anterior and posterior restorations (including occlusal surfaces) ● Core Build-ups ● Splinting ● Indirect restorations including inlays, onlays and veneers
Raw Material	- Bis-GMA - UDMA	- Bis-GMA - UDMA

	- Bis-EMA - TEGDMA - 4-EDAB - Camphorquinone - BP - BHT - Barium Glass - Silica - PVP	- Bis-EMA - TEGDMA - PEGDMA - Silane treated ceramic - Silane treated silica - Silane treated zirconia
Principle of Operation	All shades are radiopaque	All shades are radiopaque
Performance Standard Conformance	Conformed to ISO 4049	Conformed to ISO 4049
Biocompatibility	Yes	Yes
Intended Operator	Dentist	Dentist
Shelf Life	3 years	3 years

Conclusion:

Based on documentation supplied with this submission, conclusions drawn from the testing results demonstrate that the subject device is substantially equivalent to our legally marketed primary predicate device.