October 8, 2024

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

Re: K242014
Trade/Device Name: Jet Flow Bulk
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBC
Dated: July 10, 2024
Received: July 10, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242014

Device Name

Jet Flow Bulk

Indications for Use *(Describe)*

- Base under Class I and II direct restorations
- Pit and fissure sealant
- Class III and V restorations
- Repair of resin, porcelain and acrylic temporary materials
- Liner under direct restorative materials

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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K24204 - 510(k) Summary

Submitter
META BIOMED CO., LTD.
Suk Song Oh
270, Osongsaengmyeong 1-ro, Osong-eup,
Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,
South Korea
Email: ef1459@metabiogw.bizmeka.com
Phone: +82-43-230-8841
Fax: +82-43-217-1983

Official Correspondent
Withus Group Inc
April Lee
106 Superior,
Irvine, CA 92620
USA
Email: withus6664@gmail.com
Phone: 1-909-274-9971
Fax: 1-909-460-8122

Device Information

- Trade Name: Jet Flow Bulk
- Classification Name: Material, Tooth Shade, Resin
- Common Name: Tooth shade resin material
- Product Code: EBF
- Panel: Dental
- Regulation Number: 21 CFR 872.3690
- Device Class: Class II
- Date prepared: 06/26/2024

Predicate Devices:

- K120453, FILTEK BULK FILL FLOWABLE RESTORATIVE by 3M ESPE DENTAL PRODUCTS

Device Description

- Jet Flow Bulk is a low viscosity, visible-light activated, flowable. This low stress flowable material is semi-translucent enabling up to a depth of 3~5mm at a time.

- Jet Flow Bulk is packaged in disposable tips and two syringes that include restorative materials.

- The shades offered with Jet Flow Bulk are Universal(U), Dentin(D), Al, A2, A3.

- Jet Flow Bulk contains bisGMA, UDMA, bisEMA.

- The fillers are a combination of ytterbium trifluoride filler with a range of particle sizes from 0.053 to 6.76 microns and silica with a particle size range of 0.04 to 0.452 μm. The inorganic filler loading is approximately 35.6 vol.% (61.0wt.%).

Indications for Use

- Base under Class I and II direct restorations
- Pit and fissure sealant
- Class III and V restorations
- Repair of resin, porcelain and acrylic temporary materials
- Liner under direct restorative materials

Non-clinical Testing

The following testing was conducted on our subject device:

- Biocompatibility Tests according to EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-23:2021, EN ISO 7405:2018
- 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: ASTM-F1980

Summary of Technological Characteristics:

The subject device and the predicate device have the same intended use and have 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 predicate devices in raw materials, however, the test results provided in this submission support that it is substantially equivalent to the predicate device.

	Subject Device	Predicate Device
Manufacturer	Meta Biomed Co., Ltd.	3M ESPE DENTAL PRODUCTS
Device Name	Jet Flow Bulk	FILTEK BULK FILL FLOWABLE RESTORATIVE
510(k) Number	N/A	K120453
Classification Name	Material, Tooth Shade, Resin	Material, Tooth Shade, Resin
Product Code	EBF	EBF
Regulation Number	21 CFR 872.3690	21 CFR 872.3690
Indications for use	• Base under Class I and II direct restorations • Pit and fissure sealant • Class III and V restorations • Repair of resin, porcelain and acrylic temporary materials	• Base under Class I and II direct restorations • Liner under direct restorative materials • Pit and fissure sealant • Restoration of minimally invasive cavity preparations (including small, non-stress-bearing occlusal restorations) • Class III and V restorations

	• Liner under direct restorative materials	• Undercut blockout • Repair of small enamel defects • Repair of small defects in esthetic indirect restorations • Repair of resin and acrylic temporary materials • As a core build-up where at least half the coronal tooth structure is remaining to provide structural support for the crown
Raw Material	Resin: - Bis-EMA, - Bis-GMA, - UDMA, - TCDDMA. Filler: - Barium Glass, - Feldspar, - Silica, - Ytterbium fluoride. Total inorganic filler: 61% weight, 35.6% volume	Resin: - Bis-EMA, - Bis-GMA, - UDMA, - Substituted Dimethacrylate, - TEGDMA. Filler: - Silane treated ceramic, - Ytterbium fluoride, Total inorganic fillers: 64.5% weight, 42.5% volume.
Principle of Operation	Jet Flow Bulk contains bisGMA, UDMA, bisEMA. The fillers are a combination of ytterbium trifluoride filler with a range of particle sizes from 0.053 to 6.76 microns and silica with a particle size range of 0.04 to 0.452 μm. The inorganic filler loading is approximately 35.6 vol.% (61.0wt.%). When irradiated by light, the methacrylate functionalities of the resins and fillers undergo, in conjunction with the photo initiator system, a light induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.	Filtek Bulk Fill Flowable Restorative contains bisGMA, UDMA, bisEMA(6) and Procrylat resins. The fillers are a combination of ytterbium trifluoride filler with a range of particle sizes from 0. 1 to 5.0 microns and zirconia/silica with a particle size range of 0.0 1 to 3.5 μm. The inorganic filler loading is approximately 64.5% by weight (42.5% by volume). A dental adhesive is used to permanently bond the restoration to the tooth structure. When irradiated by light, the methacrylate functionalities of the resins and fillers undergo, in conjunction with the photo initiator system, a light induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.
Performance Standard	Conformed to EN ISO 4049	Conformed to EN ISO 4049, EN ISO 6874
Radiopaque	O	O
Depth of cure	> 2.5 ㎜ (U: 5 ㎜, D: 5 ㎜, A1: 3.27 ㎜, A2: 3.31 ㎜, A3: 3.07 ㎜)	4mm

Flexural strength	≥ 80MPa (106.26MPa)	126.5MPa
Water sorption & Solubility	≤ 40 μg/㎜³ (13.48 μg/㎜³) ≤ 7.5 μg/㎜³ (1.14 μg/㎜³)	(26.52 μg/㎜³) (5.98 μg/㎜³)
Sensitivity to ambient light	Physically homogeneous(Pass)	Physically homogeneous
Shade and Colour stability	Shade: The shade of the sample shall be matched with shade guide.(Pass) Colour Stability: The sample shall be no colour change.(Pass)	The shade of the sample shall be matched with shade guide. The sample shall be no colour change.
Biocompatibility	Yes	Yes
Intended Operator	Dentist	Dentist
Sterility	Non-sterile	Non-sterile
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, Jet Flow Bulk is substantially equivalent to our legally marketed predicate device.