April 13, 2023

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

Re: K230010
Trade/Device Name: ADSEAL Plus
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: February 13, 2023
Received: February 13, 2023

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,

Bobak Shirmohammadi -S

For Michael Adjodha, M.ChE.,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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230010

Device Name
ADSEAL Plus

Indications for Use *(Describe)*
ADSEAL Plus is a biocompatible root canal sealer for permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points).

ADSEAL Plus is intended for use by qualified healthcare personnel trained in its use.

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 K230010

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Device Information

- Trade Name: ADSEAL Plus
- Classification Name: resin, root canal filling
- Product Code: KIF
- Panel: Dental
- Regulation Number: 21 CFR 872.3820
- Device Class: Class II
- Date prepared: 01/03/2023

Predicate Devices:

- K042769, ADSEAL ROOT CANAL SEALER by Meta Biomed Co., Ltd.

Device Description

ADSEAL Plus root canal sealer is a two component paste:paste device based upon epoxy-amine resin chemistry. This sealer is easy to mix and adapts closely to the walls of the prepared root canal and provides outstanding long-term dimensional stability with minimal shrinkage upon setting.

The device consists of two components, the epoxy resin paste (Paste A) and the amine-containing paste (Paste B); portions of which are mixed prior to insertion into the root canal. This two component system reacts via an epoxide-amine chemical reaction to cause setting. It may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points).

Paste A and Paste B are contained, separately, with the chambers of a two component plastic syringe, packaged with a disposable applicator.

The ADSEAL Plus device is similar in design, materials and intended use to other 510(k) cleared devices which are in commercial distribution.

Indication for Use

ADSEAL Plus is a biocompatible root canal sealer for permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points).

ADSEAL Plus is intended for use by qualified healthcare personnel trained in its use.

Non-clinical Testing

The following testing was conducted on our subject device:

- Biocompatibility Tests according to ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2017.
- Performance tests such as extraneous matter and package according to ISO 6876:2012.
- Shelf Life test: ISO 6876 tests (setting time, flow and Solubility)

Summary of Technological Characteristics:

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

	Subject Device	Predicate Device
Manufacturer	Meta Biomed Co., Ltd.	Meta Biomed Co., Ltd.
Device Name	ADSEAL Plus	Adseal
510(k) Number	N/A	K042769
Classification Name	resin, root canal filling	resin, root canal filling
Product Code	KIF	KIF
Regulation Number	21 CFR 872.3820	21 CFR 872.3820
Indications for use	ADSEAL Plus is a biocompatible root canal sealer for permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points). ADSEAL Plus is intended for use by qualified healthcare personnel trained in its use.	Adseal is a biocompatible root canal sealer for permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points). ADSEAL is intended for use by qualified healthcare personnel trained in its use.

Raw Material	Base 1. Poly(Bisphenol A-co-epichlorohydrin), glycidyl end-capped 2. 2-Hydroxyethyl salicylate 3. Zirconium Dioxide 4. Calcium Phosphate Catalyst 1. Poly(1,4-butanediol) bis(4-aminobenzoate) 2. 1,3-benzenedimethan amine 3. Poly(propylene glycol) bis(2-aminopropyl ether) 4. Triethanolamine 5. Zirconium Dioxide 6. Calcium Phosphate 7. Calcium Oxide 8. Ferric Oxide Hydrate (Yellow Iron Oxide)	Base 1. Poly(Bisphenol-A-co-epichlorohydrin),glycidyl end capped 2. Ethylene glycol monosalicylate 3. Calcium phosphate 4. Bismuth subcarbonate 5. Zirconium oxide Catalyst 1. Poly(1,4-butanediol) Bis(4-aminobenzoate) 2. Triethanolamine 3. Calcium phosphate 4. Bismuth Subcarbonate 5. Zirconium oxide 6. Calcium oxide
Principle of Operation	ADSEAL Plus is a root canal filler sealer that is completely mixed with a root canal filling resin sealer used for dental treatment and is used together with a sealing point (gertera differential) to permanently fill the root canal.	ADSEAL is a root canal filler sealer that is completely mixed with a root canal filling resin sealer used for dental treatment and is used together with a sealing point (gertera differential) to permanently fill the root canal.
Performance Standard	Conformed to ISO 6876	Conformed to ISO 6876
Flowability	31mm	44mm
Radio-opacity	4.25mm	5.44mm
Biocompatibility	Yes	Yes
Intended Operator	Dentist	Dentist
Sterility	Non-sterile	Non-sterile
Shelf Life	2 years	2 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 predicate device.