May 29, 2019

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

Re: K190510
Trade/Device Name: GuttaSil
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF, EKM
Dated: February 20, 2019
Received: March 1, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Malvina B Eydelman, M.D.
Director
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)*
K190510

Device Name
GuttaSil

Indications for Use *(Describe)*
GuttaSil is a material for permanent obturation of root canals after vital extirpation and after treatment of pulpal gangrene and temporary filling of the canal.

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

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: GuttaSil
- Classification Name: resin, root canal filling
- Primary Product Code: KIF
- Secondary Product Code: EKM
- Panel: Dental
- Regulation Number: 21 CFR 872.3820
- Device Class: Class II
- Date prepared: 05/09/2019

Predicate Devices:

The subject device is substantially equivalent to the following predicate devices:

Primary Predicate

- K032662, GUTTAFLOW manufactured by COLTENE/WHALEDENT GMBH & CO. KG

Reference Devices

- K042769, ADSEAL ROOT CANAL SEALER manufactured by META BIOMED CO., LTD.
- K171449, METACEM manufactured by META BIOMED CO., LTD.

Device Description

GuttaSil, a product in the form of a paste which combines gutta-percha with a sealer. The gutta-percha powder is mixed in a matrix of polyvinylsiloxane. It is convenient since sealing and obturation are simultaneously possible without heating and the root canal can be filled in a quick manner. This device contains a syringe, auto-mix& Endo tips, spatula, and mixing pads.

Indication for Use

GuttaSil is a material for permanent obturation of root canals after vital extirpation and after treatment of pulpal gangrene and temporary filling of the canal.

Non-clinical Testing

The following testing was conducted on our subject device:

- Biocompatibility Tests according to ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2006.
- Performance tests such as Appearance, Weight, Packaging, Flow, Working Time, Setting Time, Film Thickness, Solubility, Radio-opacity according to ISO 6876:2012.
- Shelf Life test: ISO 6876 tests (appearance, package, flow, setting time, 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, both devices are silicone based and 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.	GuttaFlow
Device Name	GuttaSil	Coltene/Whaledent GMbH & Company KG
510(k) Number	NA	K032662
Classification Name	resin, root canal filling	resin, root canal filling
Product Code	KIF, EKM	KIF, EKM
Regulation Number	21 CFR 872.3820	21 CFR 872.3820
Indications for use	GuttaSil is a material for permanent obturation of root canals after vital extirpation and after treatment of pulpal gangrene and temporary filling of the canal.	GuttaFlow is a material for permanent obturation of root canals after vital extirpation and after treatment of pulpal gangrene and temporary filling of the canal.

Raw Material	Gutta-percha powder polydimethylsiloxane platinum catalyst zirconium dioxide micro-silver (preservative) colouring.	Gutta-percha powder polydimethylsiloxane platinum catalyst zirconium dioxide micro-silver(preservative) colouring
Principle of Operation	a cold flowable filling system for root canals.	a cold flowable filling system for root canals
Performance Standard Conformance	Conformed to ISO 6876	Conformed to ISO 6876
Biocompatibility	Yes	Yes
Delivery Forms	Single Paste	Single Paste
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 the legally marketed predicate device.