DMG Chemisch-Pharmazeutische Fabrik GmbH
Pamela Papineau
Consultant
Delphi Medical Device Consulting, Inc.
5 Whitcomb Ave
Ayer, Massachusetts 01432

Re: K213201
Trade/Device Name: DeltaFil, DeltaFil Conditioner
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: April 21, 2022
Received: April 27, 2022

Dear Pamela Papineau:

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 Michael E. Adjodha, M.ChE.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213201

Device Name
DeltaFil, DeltaFil Conditioner

Indications for Use *(Describe)*

DeltaFil (in capsule) is used for geriatric and pediatric restorative filling procedures. The product is designed for use in final restorations of Class I, II, III, and V of deciduous teeth and as a long - term restorative in non-load bearing areas of Class I and II carious lesions. It is also used as a restorative and sandwich material for heavy stress in Class I and II cavities. DeltaFil can also be used as a core build-up material.

DeltaFil Conditioner:
• Treatment of the smear layer
• Conditioning of the cavity

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.

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DeltaFil 510(k) Summary (revised)

General Information

Preparation date: 31 May 2022

Owner's Name: DMG Chemisch-Pharmazeutische Fabrik GmbH
(FDA Registration 8044164)
Address: Elbgaustrasse 248
22547 Hamburg
Germany
Telephone Number: 011-49-40-84006-0
Fax Number: 011-49-40-84006-222
Contact Person: Stephan Schaefer

Subject Device Name: DeltaFil
Trade Name: DeltaFil, DeltaFil Conditioner
Common/Usual Name: Dental Cement and Conditioner
Product Codes: EMA
Regulations: 21 CFR 872.3275 (Dental Cement)
Device Classification: II

Predicate Devices:
Trade Name: Fuji IX GP (GC America, Inc.)
Common/Usual Name: Dental Cement
Product Code: EMA
Regulation: 21 CFR 872.3275 (Dental Cement)
Device Classification: II
Premarket Notification: K961448

Trade Name: Ketac Conditioner (3M ESPE GmbH)
Common/Usual Name: Tooth Conditioner
Product Code: EMA
Regulation: 21 CFR 872.3275 (Dental Cement)
Device Classification: II
Premarket Notification: K872984

Reference Device:
Trade Name: DiaEtch (Diadent Group International)
Common/Usual Name: Resin Tooth Bonding Agent
Product Code: KLE
Regulation: 21 CFR 872.3200 (Resin Tooth Bonding Agent)
Device Classification: II
Premarket Notification: K192273

Device Description
DeltaFil consists of a radiopaque glass ionomer restorative material supplied in capsule form (DeltaFil in capsule), and a compatible tooth conditioner (DeltaFil Conditioner). DeltaFil Conditioner

and DeltaFil (in capsule) are used together for the creation of permanent or temporary dental restorations as described in the device labelling. DeltaFil is available in Vita shades A1, A2, A3, A3.5, and A4.

DeltaFil (in capsule) is a two-part powder/liquid glass polyalkenoate restorative cement as defined in ISO 9917-1:2006 *Dentistry – Water-Based Cements – Part 1: powder/liquid acid- base cements*. The powder and liquid components are supplied in the correct mixing ratio in disposable "Applicap" capsules for use with the DMG Applicap Dispenser. DeltaFil Conditioner is a 10% aqueous polyacrylic acid solution, which is applied to the prepared tooth surface prior to placement of the mixed DeltaFil (in capsule) material. DeltaFil Conditioner improves the adhesive bond between the tooth tissue and the restorative cement material by treating the smear layer and conditioning the prepared cavity.

Indications for Use

DeltaFil (in capsule) is used for geriatric and pediatric restorative filling procedures. The product is designed for use in final restorations of Class I, II, III, and V of deciduous teeth and as a long - term restorative in non-load bearing areas of Class I and II carious lesions. It is also used as a restorative and sandwich material for heavy stress in Class I and II cavities. DeltaFil can also be used as a core build-up material.

DeltaFil Conditioner:

- Treatment of the smear layer
- Conditioning of the cavity

Substantial Equivalence / Comparison of Technical Characteristics with the Predicate Device

The predicate devices are the GC Fuji IX GP cleared in K961448, and the 3M Espe Ketac Conditioner cleared in K872984. A summary comparison of the subject and predicate device systems is provided in the substantial equivalence table below.

Substantial Equivalence Comparison Table: DeltaFil (in capsules)

Attribute	Proposed Device DMG DeltaFil (in capsule) (current submission)	Predicate Device GC Fuji IX GP (K961448)	Similarities and Differences
Common Name	Restorative Dental Cement and Tooth Conditioner	Restorative Dental Cement and Tooth Conditioner	Same
Classification Name	Dental Cement	Dental Cement	Same
Device Class	II	II	Same
Regulation	21 CFR 872.3275	21 CFR 872.3275	Same
Regulation Name	Dental Cement	Dental Cement	Same
Product Code	EMA	EMA	Same

Attribute	Proposed Device DMG DeltaFil (in capsule) (current submission)	Predicate Device GC Fuji IX GP (K961448)	Similarities and Differences
Indications for Use	DeltaFil (in capsule) is used for geriatric and pediatric restorative filling procedures. The product is designed for use in final restorations of Class I, II, III, and V of deciduous teeth and as a long - term restorative in non-load bearing areas of Class I and II carious lesions. It is also used as a restorative and sandwich material for heavy stress in Class I and II cavities. DeltaFil can also be used as a core build-up material.	GC Fuji IX GP is used for geriatric and pediatric restorative filling procedures. The product is designed for use in final restorations of Class I, II, III, and V of deciduous teeth and as a long - term restorative in non-load bearing areas of Class I and II carious lesions. It is also used as an immediate restorative and sandwich material for heavy stress in Class I and II cavities. FUJI IX GP can also be used as a core build-up material.	Same
Use Environment	Dental office/clinic	Dental office/clinic	Same
Material Composition	Radiopaque glass ionomer cement supplied in capsules	Radiopaque glass ionomer cement supplied in capsules	Same
Principle of Operation	DeltaFil (in capsule) is a two-part powder-liquid glass ionomer polyalkenoate restorative dental cement as defined in ISO 9917-1:2007 *Dentistry – Water-Based Cements – Part 1: powder/liquid acid-base cements.* DeltaFil Conditioner is applied to condition the prepared tooth surface prior to placement of the mixed DeltaFil Capsule material.	GC Fuji IX GP is a two-part powder-liquid glass ionomer polyalkenoate restorative dental cement as defined in ISO 9917-1:2007 *Dentistry – Water-Based Cements – Part 1: powder/liquid acid-base cements.*	Same
Supplied in Mixing Capsules?	Yes	Yes	Same
Capsule Dispenser Available?	Yes	Yes	Same
Powder:Liquid Ratio	4.96:1	0.40:0.11	Similar
Mixing Time (sec)	10	10	Same

Attribute	Proposed Device DMG DeltaFil (in capsule) (current submission)	Predicate Device GC Fuji IX GP (K961448)	Similarities and Differences
Working Time (min.) at 23ºC, inclusive of mixing time (sec)	120	120	Same
Net Setting Time (max.) at 37ºC, exclusive of mixing time (sec)	240	140	Similar
Compressive Strength (MPa) (after 24 hrs)	≥ 180	220	Similar; both meet ISO 9917-1 requirement (≥ 100 MPa)
Radiopacity	200 %Al	3.7 mm	Similar; both meet ISO 9917-1 requirement (200 %Al = 2 mm)
Acid Erosion (mm)	≤ 0.1	0.21	Similar; DeltaFil meets ISO 9917-1 requirement (≤ 0.17 mm)
Shear Bond Strength on Dentin (MPa) (after 24 hrs)	4.9 ± 1.3	5.1 ± 2.1	Similar for samples prepared with compatible Conditioner; no applicable ISO 9917-1 requirement
Shear Bond Strength on Enamel (MPa) (after 24 hrs)	13.6 ± 2.4	11.8 ± 7.7	Similar for samples prepared with compatible Conditioner; no applicable ISO 9917-1 requirement
Acid Soluble Lead Content (ppm)	≤ 100	unknown	Similar; DMG material meets ISO 9917-1 requirement (≤ 100 ppm)
Opacity $C_{0,70}$ (%)	0.35 – 0.9	unknown	Similar; DMG material meets ISO 9917-1 requirement (0.35 – 0.9 %)
Biocompatibility	ISO 10993	ISO 10993	Same
Single Use / Reusable	Single Use	Single Use	Same
Sterilization / Reprocessing	Non-sterile device; no reprocessing requirements	Non-sterile device; no reprocessing requirements	Same
Software	Device does not contain software	Device does not contain software	Same

Attribute	Proposed Device DMG DeltaFil (in capsule) (current submission)	Predicate Device GC Fuji IX GP (K961448)	Similarities and Differences
Electrical Safety & EMC	Not applicable	Not applicable	Same

Substantial Equivalence Comparison Table: DeltaFil Conditioner

Attribute	Proposed Device DeltaFil Conditioner (current submission)	Predicate Device 3M Espe Ketac Conditioner (K872984)	Similarities and Differences
Common Name	Tooth Conditioner	Tooth Conditioner	Same
Classification Name	Dental Cement	Dental Cement	Same
Device Class	II	II	Same
Regulation	21 CFR 872.3275	21 CFR 872.3275	Same
Regulation Name	Dental Cement	Dental Cement	Same
Product Code	EMA	EMA	Same
Indications for Use	• Treatment of the smear layer • Conditioning of the cavity	Dentin pretreatment prior to filling with glass ionomer cement	Same
Use Environment	Dental office/clinic	Dental office/clinic	Same
Material Composition	10% aqueous polyacrylic acid Blue colorant	20 - 30% aqueous polyacrylic acid Blue colorant	Same
Principle of Operation	DeltaFil Conditioner improves the adhesive bond between the tooth tissue and the restorative cement material by treating the smear layer and conditioning the prepared cavity.	Ketac Conditioner improves the adhesive bond between the tooth tissue and the restorative cement material by treating the smear layer and conditioning the prepared cavity.	Same
Technological Characteristics	Mild PAA acid solution applied to the prepared tooth surface removes the smear layer, thereby improving direct contact between the restorative material and intact dentin structure. Evidence is demonstrated through increased bond strength for finished DeltaFil restorations using DeltaFil Conditioner.	Mild PAA acid solution applied to the prepared tooth surface removes the smear layer, thereby improving direct contact between the restorative material and intact dentin structure.	Same
Shear Bond Strength on Dentin*	4.9 ± 1.3 (with Conditioner) 4.4 ± 3.7 (without Conditioner)	5.1 ± 2.1 (with Conditioner*) 6.5 ± 1.5 (without Conditioner)	Similar

Attribute	Proposed Device DeltaFil Conditioner (current submission)	Predicate Device 3M Espe Ketac Conditioner (K872984)	Similarities and Differences
Shear Bond Strength on Enamel*	13.6 ± 2.4 (with Conditioner) 13.6 ± 6.5 (without Conditioner)	11.8 ± 7.7 (with Conditioner*) 10.6 ± 4.5 (without Conditioner)	Similar
Biocompatibility	ISO 10993	ISO 10993	Same except for blue colorant. Reference device K192273 (Diadent DiaEtch) used to confirm biological safety of methylene blue colorant.
Single Use / Reusable	Single Use	Single Use	Same
Sterilization / Reprocessing	Non-sterile device; no reprocessing requirements	Non-sterile device; no reprocessing requirements	Same
Software	Device does not contain software	Device does not contain software	Same
Electrical Safety & EMC	Not applicable	Not applicable	Same

* Predicate SBS data for GC Fuji IX GP with and without the compatible GC Cavity Conditioner

Non-clinical Performance Testing

Performance data demonstrated that DeltaFil (in capsule) and DeltaFil Conditioner meet all predetermined acceptance criteria contained in the product specification and are suitable for their intended use. The risks associated with the use of the new devices were found acceptable when evaluated in accordance with ISO 14971. Risks and benefits associated with the proposed and the predicate device are the same. Design verification and validation activities consisted of physical testing, biocompatibility evaluation, and stability (shelf life) validation.

Comparison of Technological Characteristics with the Predicate Devices

The general material type, intended use, and performance specifications of DeltaFil (in capsule) and DeltaFil Conditioner are substantially equivalent to the predicate devices, GC Fuji IX GP and 3M Espe Ketac Conditioner. DeltaFil (in capsule) and GC Fuji IX GP are two-part powder-liquid glass ionomer polyalkenoate restorative dental cement as defined in ISO 9917-1:2007 *Dentistry – Water-Based Cements – Part 1: powder/liquid acid-base cements*. Both DeltaFil (in capsule) and GC Fuji IX GP are supplied in capsules that are briefly mixed by the user in a standard dental capsule mixer prior to dispensing.

DeltaFil Conditioner and 3M Espe Ketac Conditioner are both mild, blue-tinted aqueous solutions of polyacrylic acid intended to enhance the bond between the glass ionomer restorative cement and the tooth surface by treating the smear layer to condition the cavity. DeltaFil Conditioner is intended for use prior to the application of DeltaFil (in capsule). The Diadent DiaEtch cleared in K192273 is cited

as a reference device to confirm biological safety for methlylene blue pigment used to enhance the visibility of dental cavity pretreatments.

Conclusion

The DMG Chemisch-Pharmazeutische Fabrik GmbH DeltaFil (in capsule) and DeltaFil Conditioner meet all pre-determined acceptance criteria of the testing performed to confirm substantial equivalence to the predicate devices.