February 6, 2023

3M ESPE Dental Products
% Prithul Bom
Most Responsible Personal
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K230270
Trade/Device Name: 3M™ VitCal Liner/Base
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium hydroxide cavity liner
Regulatory Class: Class II
Product Code: EJK
Dated: January 31, 2023
Received: January 31, 2023

Dear Prithul Bom:

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,

Michael E. Adjodha -S

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.

Submission Number *(if known)*

K230270

Device Name

3M™ VitCal Liner/Base

Indications for Use *(Describe)*

3M VitCal Liner/Base is indicated for lining and basing applications under dental restorations.

3M VitCal Liner/Base is also indicated for direct pulp capping.

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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3M™ VitCal Liner/Base – 510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 CFR §807.92

Submitter Information

510(k) Submitter…….…..…… 3M ESPE Dental Products
2510 Conway Avenue
St. Paul, MN 55144, USA
Establishment Registration No.: 3005174370

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Submission Date……27th January, 2023

Subject Device Information

Proprietary Trade Name.……. 3M™ VitCal Liner/Base

Device Name…….…..……...…Liner/Base

Common Name……. Liner/Base, Dental Cement

Classification Name……..… Dental Cement

Regulation Number……. 21 CFR § 872.3275

Product Code…….…....……. EMA

Classification Panel……..…. Dental Products

Classification…….....….Medical Device, Class II

Predicate Devices:

Product Name	**TheraCal LC® (Primary Predicate)**	**3M™ Vitrebond™ Plus (Secondary Predicate)**
Manufacturer	Bisco, Inc. 1100 WEST IRVING PARK RD. SCHAUMBURG, IL 60193	3M ESPE Dental Products 2510 Conway Avenue Saint Paul, MN, 55144
510(k) Number	K063237	K011200
Device Class	2	2

Description of Device

3M VitCal liner/base is a two-part paste/paste, light-cured system. The paste/paste materials are contained in a Micro-Mix Syringe Dispensing System. This dispensing system provides simultaneous dispensing and mixing of each component for a consistent mix and direct application into the mouth.

The composition is a combination of a resin-modified glass ionomer and calcium-based material. The first paste contains a radiopaque fluoro-aluminosilicate glass and calcium filler. The second paste contains a modified polyalkenoic acid. VitCal liner/base provides the major benefits of glass ionomer cements including adhesion to the tooth structure and sustained fluoride release. Additionally, VitCal liner/base offers a high pH environment and a combination of a prolonged working time with an on-demand set time achieved by light curing.

3M VitCal Liner/Base meets the requirements for ISO 9917-2 Class 2 Liner/Base.

Indications for Use

3M VitCal Liner/Base is indicated for lining and basing applications under dental restorations.
3M VitCal Liner/Base is also indicated for direct pulp capping.

Substantial Equivalence

Substantial equivalency of 3M VitCal Liner/Base to TheraCal LC and 3M Vitrebond Plus is made on the basis of intended/indicated use, technological characteristics, and performance testing. Differences in technological characteristics of the subject device and the primary predicate devices have been evaluated in accordance with the Agency's *Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* dated July 28, 2014. In accordance with this guidance document, a "different question of safety or effectiveness" means a question raised by the technological characteristics of the new device that was not applicable to the predicate device *and poses a significant* safety or effectiveness concern for the new device. Differences in the technological characteristics of 3M VitCal, TheraCal LC, and 3M Vitrebond Plus do not raise different questions of safety or effectiveness.

Substantial Equivalence - Intended/Indicated Use				
Device	**3M VitCal Liner/Base (Subject Device)**	**TheraCal LC (Primary Predicate, K063237)**	**3M Vitrebond Plus (Secondary Predicate, K011200)**	**Comparison**
Product Code	EMA - Cement, Dental	EJK - Liner, Cavity, Calcium Hydroxide	EMA - Cement, Dental	The product code is the same for 3M VitCal Liner/Base and 3M Vitrebond Plus.
Regulation	872.3275 - Dental cement	872.3250 - Calcium hydroxide cavity liner	872.3275 - Dental cement	The regulation is the same for 3M VitCal Liner/Base and 3M Vitrebond Plus.
Intended Use per Regulation	872.3275(b)(1) Dental cement other than zinc oxide-eugenol is a device composed of various materials other than zinc oxide-eugenol intended……to be applied to a tooth to protect the tooth pulp.	872.3250(a) A calcium hydroxide cavity liner is a device material intended to be applied to the interior of a prepared cavity before insertion of restorative material, such as amalgam, to protect the pulp of a tooth.	872.3275(b)(1) Dental cement other than zinc oxide-eugenol is a device composed of various materials other than zinc oxide-eugenol intended……to be applied to a tooth to protect the tooth pulp.	Dental cements and calcium hydroxide cavity liners are both intended for use in dental restorative procedures to protect the pulp.
Indications for Use – 510(k)	Liner/base, Pulp capping	Liner, Pulp capping agent	Vitrebond Plus liner/base is indicated for lining and basing applications under the following restorations: Composite; Amalgam; Ceramic; Metal	3M VitCal Liner/Base and TheraCal LC have the same indications for use. Both devices are indicated for use in pulp capping and lining/basing applications. Although not explicitly stated in the 510(k) clearance, TheraCal LC is currently labeled for basing applications. All three devices are indicated for use in liner/base applications.

Substantial Equivalence – Technological Characteristics				
Device	**3M VitCal Liner/Base (Subject Device)**	**TheraCal LC (Primary Predicate, K063237)**	**3M Vitrebond Plus (Secondary Predicate, K011200)**	**Comparison**
Number of Components	Two (paste/paste)	One	Two (paste/liquid)	3M VitCal Liner/Base differs from TheraCal LC but is similar to Vitrebond Plus. This difference does not raise different questions about safety or effectiveness as two-part liner/base, and pulp capping materials are common, established technology in dental preparations, i.e., Vitrebond Plus.
ISO 9917-2 Class	Class 2, Base or Lining	Not applicable.	Class 2, Base or Lining	TheraCal LC does not claim compliance to ISO 9917-2 *Dentistry – Water-based cements Part 2: Resin-modified cements.* Both 3M VitCal Liner/Base and Vitrebond Plus meet the requirements for working time, flexural strength, and radiopacity as ISO 9917-2 Class 2 Base/Liner materials. This difference does not raise different questions of safety or effectiveness.
Working Time per Annex A of ISO 9917-2	≥1.5 minutes	Not labeled	≥1.5 minutes	
Flexural Strength per Annex C of ISO 9917-2	≥10 MPa	Not labeled	≥10 MP	
Radiopacity per Annex D of 9917-2 and ISO 13116	≥1.0 mm Aluminum Standard (mmAl)	≥1.0 mm Aluminum Standard (mmAl)	≥1.0 mm Aluminum Standard (mmAl)	
Setting Mechanism	Light cure	Light cure	Light cure	All devices are light-cured.
Cure Time and Intensity	Layers of 1 mm or less for 20 seconds for a curing light with >1000 mW/cm^2 or 30 seconds for a curing light with 400-1000 mW/cm^2	Layers of 1mm or less for 20 seconds; light intensity not specified in IFU.	Layers of 1.5 mm or less for 20 seconds to a 3M curing light manufactured by 3M or other curing unit of comparable intensity	Both 3M VitCal Liner/Base and TheraCal LC are cured incrementally in layers of 1mm or less.
Calcium Release	> 0 µg/g	> 0 µg/g	Does not release calcium	Both 3M VitCal Liner/Base and TheraCal LC release calcium. Vitrebond Plus is not designed with this characteristic.
Fluoride Release	> 0 µg/g	Does not release fluoride	> 0 µg/g	TheraCal LC does not release fluoride, but Vitrebond Plus does. This difference does not raise different questions of safety or effectiveness.
Phosphate Release	> 0 µg/g	Does not release phosphate	Does not release phosphate	Vitrebond Plus and TheraCal LC are not designed to release phosphate; however, this difference does not raise any new questions about safety or effectiveness as dental materials with the same intended use as 3M VitCal Liner/Base also release phosphate (i.e., Lime-Lite™ ENHANCED[1] cleared under K153249).
Dispensing System	Intra-oral, multi-unit Micro-Mix syringe with single-use tips	Intra-oral, multi-unit syringe with single-use tips	Extra-oral, multi-unit clicker	The essential design is the same. All devices are dispensed from a multi-unit syringe or clicker, and 3M VitCal Liner/Base and TheraCal LC are dispensed intra-orally, whereas Vitrebond Plus is dispensed extra-orally. Differences do not raise any new questions of safety or effectiveness.
Sterility	Non-sterile	Non-sterile	Non-sterile	All devices are not labeled as sterile products.
Nanomaterials	Contains nanomaterial	Unknown	Contains nanomaterial	The nanomaterials in 3M VitCal Liner/Base are used in other FDA-cleared 3M dental products with similar tissue contact types, duration of use, and purpose in the formulation. Based on a review of the functions of the nanomaterials used in this product, there are no appropriate larger-scale alternatives. This difference, compared to the predicate device, does not raise different questions about safety or effectiveness.
Materials	Portland cement, silane-treated silica, methacrylate polymer, photoinitiators	Mineral trioxide aggregate, methacrylate polymer, photoinitiators	Silane-treated silica, methacrylate polymer, photoinitiators	The essential design of light-cured resin-modified dental restorative materials includes fillers, resin, and curing agents. All three products share the same essential design. Differences do not raise any new questions about safety or effectiveness.

Substantial Equivalence – Bench Test					
PHYSICAL PROPERTIES	**Specification**	**Units/ Additional Details**	**3M VitCal Liner/Base**	**TheraCal LC**	**3M Vitrebond Plus**
Compressive Strength	≥ 69 MPa	MPa	103 ± 10	Could not be cured effectively	102 ± 6
Flexural Strength	≥ 10 MPa	MPa	25 ± 3	16 ± 2	27 ± 1
Surface Hardness (Barcol)	Barcol hardness on the bottom of the sample must be ≥ 80% of the hardness on the top of the sample - Using a curing light with an approximate intensity of 950 mW/cm^2 for 20 seconds	% with curing light distance 0 mm	98 ± 8%	84 ± 3%	109 ± 15%
		% with curing light distance 7 mm	93 ± 3%	60 ± 4%	101 ± 6%
	Barcol hardness on the bottom of the sample must be ≥ 80% of the hardness on the top of the sample - Using a curing light with an approximate intensity of 400 mW/cm^2 for 30 seconds	% with curing light distance 0 mm	94 ± 4%	Not tested.	92 ± 2%
		% with curing light distance 7 mm	89 ± 11%		101 ± 8%
Radiopacity	≥ 1.0 mm Aluminum Standard (mmAl)	mmAl	1.52 ± 0.05	1.56 ± 0.01	1.33 ± 0.04
Calcium Release	> 0 µg/g (Pass/Fail)	Cumulative amount for seven days	Pass	Pass	Not applicable.
Fluoride Release	> 0 µg/g (Pass/Fail)	Cumulative amount for seven days	Pass	Not applicable.	Pass
Phosphate Release	> 0 µg/g (Pass/Fail)	Cumulative amount for seven days	Pass	Not applicable.	Not applicable.
Working Time	>1.5 minutes	minutes	2.44 ± 0.0	N/A, one part	2.5 per IFU
Shear Bond Strength to Dentin	>4 MPa	MPa, adhesion to 3M Scotchbond Universal	6 ± 3	2 ± 1	9 ± 3
		MPa, adhesion to 3M Adper Single Bond Plus Adhesive	6 ± 2	Not tested.	13 ± 1
		MPa, adhesion to 3M Scotchbond Multi-Purpose Plus Adhesive	8 ± 3	Not tested.	13 ± 2
		MPa, adhesion to Kuraray CLEARFIL™ SE BOND Adhesive	6 ± 3	Not tested.	8 ± 3
Dentin Tubule Occlusion[2]	Tag formation into dentinal tubules must be observed under scanning electron microscopy (SEM) imaging	Yes/No	Yes	Yes	Yes

[2] Only 1 lot of 3M VitCal was tested.

Confidential

Biocompatibility Assessment

VitCal Liner/Base was assessed as an external communicating device that is intended to be in contact with the body for greater than 30 days (ISO 10993, ISO 7405, FDA-2013-D-0350, and PFSB).

In accordance with the combined guidance found in ISO 10993, ISO 7405, Testing guidelines outlined in the US FDA Docket Number FDA-2013-D-0350, and Japan: PSEHB/MDED No. 0106-1 and 0612-4, the following endpoints below must be considered in the biocompatibility evaluation of this product: Physical and/or Chemical Information, Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, Acute Systemic Toxicity, Material-Mediated Pyrogenicity, Subacute Toxicity, Genotoxicity, and Implantation.

A Diplomate of the American Board of Toxicology has assessed the safety of this product and has determined that it is safe for its intended use.

Statement of Substantial Equivalence

The indications for use of 3M VitCal Liner/Base are the same as TheraCal LC and similar to Vitrebond Plus. 3M VitCal Liner/Base technological characteristics are similar but not identical to TheraCal LC and 3M Vitrebond Plus. All three devices are resin-based, radiopaque, light-cured dental materials with similar dispensing systems. Differences in technological characteristics of the subject device and the primary predicate devices have been evaluated in accordance with the Agency's Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] dated July 28, 2014. Differences in the technological characteristics of 3M VitCal Liner/Base, compared to TheraCal LC and Vitrebond Plus, do not raise significant concerns about safety or effectiveness. Bench testing was conducted to compare the performance of 3M VitCal Liner/Base to TheraCal LC and 3M Vitrebond Plus. Testing demonstrates that the safety and performance of 3M VitCal Liner/Base are substantially equivalent to the predicate device.