



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2016

Denali Corporation
Ms. Jan G. Stannard
President
134 Old Washington Street
Hanover, Massachusetts 02339

Re: K153191
Trade/Device Name: Calcium Bridge
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: II
Product Code: EBF
Dated: January 15, 2016
Received: January 19, 2016

Dear Ms. Stannard:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Tina Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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510 (k) Summary

February 26, 2016

ADDRESS	DENALI CORPORATION 134 Old Washington Street / Hanover, MA 02339-1629
OWNER/CONTACT PERSON	Dr. Jan G. Stannard TEL: 781-826-9190 / FAX: 781-826-4465 j.stannard@denalicorporation.com
TRADE NAME	Calcium Bridge
COMMON NAME	Cavity Liner, Flowable Composite
CLASSIFICATION NAME	Tooth Shade Resin Material, Class II (21 CFR 872.3690, Product Code EBF)
REGISTRATION	3006367836
PREDICATE DEVICES	Tetric EvoCeram (k042819)
EQUIVALENCE	The predicate product has been found to be substantially equivalent under the 510(k) premarket notification process as Class II Dental Devices under CFR EBF 872.3690, Tooth Shade Resin Material.
DEVICE DESCRIPTION	Calcium Bridge is a resin-based, flowable polymerizable composite paste recommended as a lining material beneath composite resins or as a preventive resin restoration (PRR) material (a minimally invasive procedure to protect a tooth). A PRR restoration is not intended to prevent caries but intended to be used in the treatment of caries. Because Calcium Bridge is highly radio-opaque this allows for easy radiographic observation compared to enamel, dentin, and possible secondary caries.
INDICATIONS FOR USE	Calcium Bridge is a resin-based composite recommended for use as a liner or initial layer beneath all composite resins, or as flowable composite in preventive resin restorations. For Use only by a Licensed Dentist. Rx Use Only.
TECHNOLOGICAL CHARACTERISTICS SUMMARY	Calcium Bridge has the same technological characteristics as the predicate device Tetric Evoceram including: design, composition, biocompatibility, performance, ageing, intended use, physical characteristics, setting time, depth of cure, radio-opacity, fluorescence ability and mechanical properties (tensile and compressive strength), as summarized in the Table below.

Summary of Characteristics of Calcium Bridge and the Predicate Product

Property	Calcium Bridge	Tetric Evoceram
Light Curing Capability, Cures Less Than 20 seconds	Cures Less Than 20 seconds	Cures Less Than 20 seconds
Radiopaque, Aluminum Equivalent to Equal 1 mm	3.5 mm Aluminum	2.0 mm Aluminum
Fluorescence, Visible Blue Glow Under UV Lighting	Visible Blue Glow Detected	Visible Blue Glow Detected
Compressive Strength (MPa)	Greater Than 250 MPa	250 MPa
Depth of Cure Greater Than 1.5 mm	Greater Than 1.5 mm	Greater Than 1.5 mm
Biocompatibility, ISO 10993-5 (Cytotoxicity)	Zone of Inhibition 0.25 cm	N/A - Not Available



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The differences between Calcium Bridge and the predicate product in the above Table are that of radiopacity and compressive strength. In this case, Calcium Bridge is more radiopaque than the predicate device. Calcium Bridge was also found to have a higher compressive strength than the predicate product. These differences do not change the performance or usage between the subject and the predicate device.

BIOCOMPATIBILITY

Calcium Bridge was found to be biocompatible according to ISO 10993-5 "Evaluation of Medical Devices-Cytotoxicity", and is consistent in formulation to Tetric EvoCeram, in its intended use and biocompatibility.

SUBSTANTIAL EQUIVALENCE DETERMINATION AND SUMMARY

Calcium Bridge is substantially equivalent in design, composition, biocompatibility (ISO 10993-5, Evaluation of Medical Devices - Cytotoxicity), performance, ageing, and intended use to Tetric EvoCeram. This assessment is based upon a comparison of the physical and mechanical characteristics (tensile strength, compressive strength), depth of cure, setting time, radio-opacity, and fluorescing ability. The results of these tests are equivalent to the values of Tetric EvoCeram.

CONCLUSIONS

Differences in the Indications For Use between the predicate device and the subject device reflect the current usage of the term "flowable composite". A flowable composite is used today for the predicate device's Indications For Use. The usage of the term flowable composite does not effect any usage or performance difference between the subject and predicate device. Calcium Bridge has been found to be substantially equivalent in design, composition, ageing, biocompatibility, performance, and intended use to Tetric EvoCeram.