



Food and Drug Administration
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Silver Spring, MD 20993-0002

February 18, 2016

DENALI CORPORATION
Dr. Jan G. Stannard
President
134 Old Washington Street
Hanover, Massachusetts, 02339

Re: K151945
Trade/Device Name: Triumph Resin Dam
Regulation Number: 21 CFR 872.6300
Regulation Name: Rubber dam and accessories
Regulatory Class: I
Product Code: EIE
Dated: January 14, 2016
Received: January 19, 2016

Dear Dr. 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 -

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



INDICATIONS FOR USE STATEMENT

510 (k) Number K151945
(if known)

Device Name

Triumph Resin Dam

Indications for Use:

Triumph Resin Dam is a resin-based, light-cured protective barrier material recommended to protect dental materials or tissues.

For Use only by a Licensed Dentist. Rx Use Only.

Please do not write below this line. Continue on another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use or Over-The-Counter Use
(Per 21 CFR 801.109)


denali corporation

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510 (k) Summary

February 17, 2016

ADDRESS DENALI CORPORATION
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OWNER/CONTACT PERSON Dr. Jan G. Stannard
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TRADE NAME Triumph Resin Dam

COMMON NAME Resin Dam

CLASSIFICATION NAME RUBBER DAM AND ACCESSORIES, CLASS I (21 CFR 872.6300, Product EIE)

REGISTRATION 3006367836

PRIMARY PREDICATE DEVICE OpalDam (k971284) Ultradent Products, Inc.
REFERENCE PREDICATE DEVICE BriteSmile (k010935), BriteSmile Inc,

EQUIVALENCE The primary predicate product has been found to be substantially equivalent under the 510(k) premarket notification process as Class I Dental Devices under CFR 872.6300, RUBBER DAM AND ACCESSORIES.

DEVICE DESCRIPTION Triumph Resin Dam is a light-cured, resin dam material recommended to block out or protect dental materials or tissues. Triumph contains polymerizable monomers that when light-cured form a protective barrier. When set the resin has a low strength allowing its removal from the protected surfaces.

INTENDED USE Triumph Resin Dam is a resin-based, light-cured protective barrier material recommended to protect dental materials or tissues. **For Use only by a Licensed Dentist. Rx Use Only.**

TECHNOLOGICAL CHARACTERISTICS SUMMARY and Intended Use Triumph Resin Dam has the same technological characteristics as the primary predicate device OpalDam including: design, similar composition, biocompatibility, performance, principle of operation, ageing, intended use, physical characteristics, setting, depth of cure and mechanical properties; compressive strength and hardness, as summarized in the table below. The inclusion of protection of dental materials does not alter its intended use nor, does it alter its function. Materials as well as tissue may be affected by bleaching actions.

COMPARISON OF TRIUMPH RESIN DAM TO PRIMARY PREDICATE PRODUCT

PROPERTY	Triumph Resin Dam	Opal Dam
Intended Use	Resin barrier used to isolate and protect dental materials and tissues.	Resin barrier used to isolate and protect dental materials and tissue
Composition	Urethane acrylates, silica, titanium dioxide, light curing chemistry.	Di-urethane di-methacrylate, filler (possibly mica), light curing chemistry.
Light Cure Capability	Yes	Yes
Light Cure Setting Time	Yes, < 20 seconds	Yes, < 20 seconds
Flexibility to allow removal in one piece, when applied around a dental tooth model	Yes	Yes



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BIOCOMPATIBILITY

Triumph Resin Dam was evaluated for biocompatibility as per ISO 10993 "Biological Evaluation of Medical Devices". Tests conducted were cytotoxicity, human skin irritation and skin sensitization. Triumph Resin Dam was found to be biocompatible. For ISO10993 Cytotoxicity Testing, Triumph Resin Dam had a Grade "0". "Reactivity, None". As per ISO 10993 "Tests for Irritation and Skin Sensitization", with respect to irritation Triumph was graded as "No reaction", with respect to Skin sensitization, Triumph was rated as Grade "0" - "No visible change". These results are summarized in the Table of Results - Biological Evaluation of Triumph Resin Dam per ISO 10993.

Results - Biological Evaluation of Triumph Resin Dam - per ISO 10993

Test Method	Description	Result
Cytotoxicity	None	0
Human Skin Irritation Test	No Reaction	0
Skin Sensitization Test	No Visible Change	0

SUBSTANTIAL EQUIVALENCE DETERMINATION AND SUMMARY

Triumph Resin Dam is substantially equivalent in design, similar composition, biocompatibility, performance, ageing, and intended use, to Opal Dam (K971284). This assessment is based upon a comparison of the physical and mechanical characteristics, depth of cure, and setting time. Formula differences between Triumph and the predicate product exist, however Triumph Resin Dam was found to be biocompatible as per ISO 10993 and has similar technological and performance characteristics as the predicate product OpalDam. The differences that exist between Opal

Dam and Triumph are that Opal Dam is harder and has less depth of cure than Triumph. Both products however are formulated to be flexible enough (not too brittle), allowing removal in one piece. This difference does not effect the ability of either material to perform as a resin barrier. Although the composition of Triumph may not be the same as OpalDam, the properties of these two materials were found to be similar. Triumph was with respect to hardness found to be more similar to the reference device, BriteSmile (k010935). In this comparison BriteSmile also like Triumph was formulated to allow removal in one piece. Again Triumph has a greater depth of cure than BriteSmile.

CONCLUSIONS

Triumph Resin Dam has been found to be substantially equivalent in design, composition, principle of operation, ageing, biocompatibility, performance, properties, and intended use, to OpalDam.