



**SUMMARY OF SAFETY AND EFFECTIVENESS DATA**

Dr Jan G Stannard  
134 Old Washington Street  
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**DEVICE**

Trade Name Clear Bravo  
Classification Name Pit and Fissure Sealant and Conditioner  
FDA Product Code EBC 872 3765

**JAN 22 2009**

**PREDICATE DEVICES**

CosmeSeal Pit and Fissure Sealant  
UltraSeal XT Pit and Fissure Sealant and Flowable Composite Kit  
Delton Clear Pit and Fissure Sealant Kit

**INDICATIONS FOR USE**

Clear Bravo is a clear, light-cured pit and fissure sealant and sealer for application to the surfaces of teeth, sealing of composite margins and temporary restorations. Clear Bravo is available in either fluoride and non-fluoride releasing formulas.

**DESCRIPTION AND INTENDED USE**

Clear Bravo is a clear, light-cured pit and fissure sealant and sealer for application to the surfaces of teeth, sealing of composite margins and temporary restorations. Clear Bravo is crystal clear which allows observation of conditions which may occur beneath the sealant. This would include possible leakage, staining and also allows the use of caries detecting devices. Clear Bravo is available in either fluoride and non-fluoride releasing formulas.

**COMPARISON WITH PREDICATE PRODUCTS**

Clear Bravo has been found to be substantially equivalent in design, composition and intended use to the products listed above.

**SAFETY AND EFFECTIVENESS**

The predicate products have been found substantially equivalent under the 510(k) premarket notification process as Class II Dental Devices under CFR 21.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 22 2009

Ms Jan G Stannard  
President  
Denali R&D Corporation  
134 Old Washington Street  
Hanover Massachusetts 02339-1629

Re K083473  
Trade/Device Name Clear Bravo  
Regulation Number 21 CFR 872.3765  
Regulation Name Pit and Fissure Sealant and Conditioner  
Regulatory Class II  
Product Code EBC  
Dated November 19, 2008  
Received November 24, 2008

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.

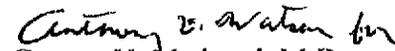
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Ginette Y. Michaud, M.D.

Acting Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



**INDICATIONS FOR USE STATEMENT**

510 (k) Number \_\_\_\_\_  
(if known)

Device Name  
**Clear Bravo**

**Indications for Use**

Clear Bravo is a clear, light-cured pit and fissure sealant and sealer for application to the surfaces of teeth, sealing of composite margins and temporary restorations. Clear Bravo is available in either fluoride and non-fluoride releasing formulas.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)

Division of Anesthesiology, General Hospital

Infection Control, Dental Devices

510(k) Number FCR 3473

Prescription Use   x    
(Per 21 CFR 801.109)

or

Over-The-Counter Use