

K 992879

NOV - 9 1999

510(k) Summary

Trade Name: Ecusit Composite Repair

Sponsor: DMG USA, Inc.
414 South State Street
Dover, DE 19901
Registration # not yet assigned

Device Generic Name: Resin tooth bonding agent

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Devices: The proposed Ecusit Composite Repair is substantially equivalent to the One Coat Bond Dentin/Enamel Adhesive System marketed by Coltene/Whaledent, Inc., which was cleared for marketing by FDA in K974906.

Product Description:

The Ecusit Composite Repair material is a single-component, methyl methacrylate-based, light-curing bonding agent specifically developed for use in intra-oral repair of poor or damaged dental composite restorations.

Indications for Use:

Ecusit Composite Repair is indicated for intra-oral repair of dental composite restorations.

Safety and Performance:

Substantial equivalence for this device was based on similarities in design and performance characteristics as well as performance testing. The materials, performance specifications and essential design characteristics of the Ecusit Composite Repair are equivalent to those of the predicate devices. In addition, shear strength and composite penetration depth data were presented for the Ecusit Composite Repair material.

Conclusion:

Based on the indications for use, technological characteristics, and comparison to predicate devices, the Ecusit Composite Repair has been shown to be safe and effective for its intended use.

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NOV - 9 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DMG USA, Incorporated
c/o Ms. Pamela Papineau
Consultant to DMG USA, Incorporated
Delphi Medical Device Consulting
5 Whitcomb Avenue
Ayer, MA 01432

Re: K992879
Trade Name: Ecusit Composite Repair
Regulatory Class: I
Product Code: KLE
Dated: August 16, 1999
Received: August 26, 1999

Dear Ms. Papineau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

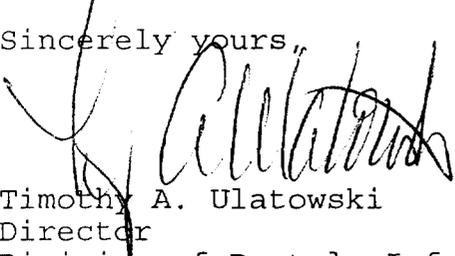
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 992879

Device Name: Ecusit Composite Repair

Indications for Use:

Ecusit Composite Repair is indicated for intra-oral repair of composite restorations.

(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)

Susan Ruane
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K 992879

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