

1K992838

NOV 15 1999

BioMat Sciences

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510(k) Summary

1. Submitter BioMat Sciences, Inc.
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Bethesda, MD 20817
Tel 301 652-3327
Fax 301 652-8827
Dr. Ivan Stangel (contact person)
August 5, 1999 (date of preparation)
2. Device Name Trade name – Adhere
Common name – Tooth bonding system
Classification name – agent, tooth bonding, resin (per CFR 872.3200)
3. Legally marketed device for which substantial equivalence is being claimed

Optibond (Kerr, 510k #K923546)
All Bond 2 (Bisco, 510k #K910860)
One Step (Bisco, 510k #K945604)
Silane Bond Enhancer (Pulpdent Corporation 510k #896659)
4. Device Description
Adhere is an adhesive system used for the bonding of directly and indirectly placed restorative materials to tooth structure. It consists of surface conditioners, primers, an adhesive resin, initiators and accessories for applying the components to tooth surfaces. After tooth conditioning, a primer is applied, and an adhesive resin overlay is subsequently placed on the surface to interact with restorative materials. Other primers are used for surface reactions with indirect restorative materials.
5. Intended Use of the Device
Adhere is used to bond restorative materials to enamel and dentin. The materials include composites, compomers, amalgam, ceramic veneers and ceramic inlays. In addition, Adhere is used to seal dentin, and reduce tooth sensitivity in non-bacterial mediated cervical lesions of teeth. Adhere is also used to promote composite bonds to ceramics and metals.
6. Technological Characteristics of Present Device Compared to Predicate Device
Adhere is substantially equivalent to other legally marketed predicate dental devices. Substantial equivalence is based on performance and the use of components found in other legally marketed tooth bonding agents.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Ivan Stangel, D.M.D., F.A.D.M., F.I.C.D.
President & Director of Research
BioMat Sciences
5612 Glenwood Road
Bethesda, MD 20817

Re: K992838
Trade Name: Adhere Conditioner, Adhere Primer, Adhere LC
Adhesive, ADH
Regulatory Class: II
Product Code: KLE
Dated: August 15, 1999
Received: August 23, 1999

Dear Mr. Stangel:

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 (Premarket 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

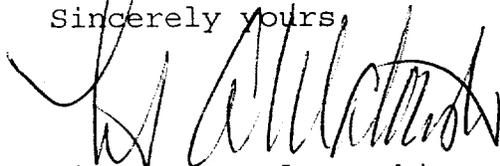
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

7. Statement of Indications for Use:

- *to promote strong bonds to enamel and dentin for a) direct restorative materials such as composite resins, compomers, amalgam, and b) resins cements used in the bonding of indirect restorative materials, such as ceramic veneers, inlays, and crowns.*
- *to seal dentinal tubules*
- *to reduce sensitivity due to exposed tubules in abrasion/erosion lesions of teeth*
- *to promote bonds between incremental layers of composite resins when building a composite restoration*
- *to bond composite resins repairs to ceramics and metals*

Prescription Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992838