

MAY 17 1999

K 990381

510(k) SUMMARY

Submitter: Parkell Products Inc.
155 Schmitt Blvd.
Box 376
Farmingdale, NY 11735
TEL: 516-249-1134
FAX: 516-249-1242

Contact: Nelson J. Gendusa, DDS
Director of Research
Parkell
155 Schmitt Blvd.
Box 376
Farmingdale, NY 11735

Submission Date: February 3, 1999

Trade Name: TOTALBOND

Common Name: Adhesive Resin Cement

Classification Name: Cement, Dental (§872.3275)

Equivalence:

Description/Intended Use: Parkell's TOTALBOND is a dual-curing adhesive cement intended for use as a luting material for bonding inlays, onlays, crowns, and bridges to properly prepared teeth. It is also indicated for use as an agent for affecting repairs of tooth-colored veneers bonded to dental alloys, either non-precious or precious. For the latter instance, the supplied kit contains a noble metal-Priming material which significantly increases the bond strength of the repair. The kit also contains a porcelain-primer that is recommended for use in repairing fractured dental porcelains. It mediates an adhesive bond between the porcelain substrate and an overlying composite resin.



MAY 17 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nelson J. Gendusa, DDS
Director of Research
Parkell Products, Incorporated
155 Schmitt Boulevard
P.O. Box 376
Farmingdale, New York 11735

Re: K990381
Trade Name: TOTALBOND
Regulatory Class: II
Product Code: EMA
Dated: April 30, 1999
Received: May 7, 1999

Dear Dr. Gendusa:

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.

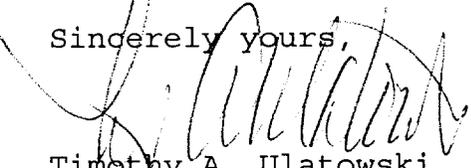
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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.

Page 2 - Dr. Gendusa

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

K990381

Page 1 of 1

510(k) Number (if known): K 990381

Device Name: TOTALBOND

Indications For Use:

A DUAL-CURING ADHESIVE CEMENT INTENDED FOR USE AS A LUTING MATERIAL FOR BONDING INLAYS, ONLAYS, CROWNS, BRIDGES, LAMINATE VENEERS, ETC. TO PROPERLY PREPARED TEETH. ALSO INDICATED AS AN AGENT FOR AFFECTING REPAIRS OF TOOTH-COLORED VENEERS BONDED TO DENTAL ALLOYS, EITHER NON-PRECIOUS OR PRECIOUS. FOR THE LATTER, THE KIT CONTAINS A NOBLE METAL PRIMING MATERIAL WHICH SIGNIFICANTLY INCREASES THE BOND STRENGTH OF THE REPAIR. THE KIT ALSO CONTAINS A PORCELAIN PRIMER THAT IS RECOMMENDED FOR USE IN REPAIRING FRACTURED DENTAL PORCELAINS. IT MEDIATES AN ADHESIVE BOND BETWEEN THE PORCELAIN SUBSTRATE AND AN OVERLYING COMPOSITE RESIN.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

Susan Rummer
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990381