MAR 2 0 2002

K020239

## 510(k) SUMMARY

**Submitter:**

Parkell, Inc.
155 Schmitt Blvd.
Box 376
Farmingdale, NY 11735
TEL: 631-249-1134
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**Contact:**

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

**Submission Date:** 15 January 2002

**Trade Name:** Touch&Bond-Plus

**Common Name:** Dentin Bonding System

**Classification Name:** Resin Tooth Bonding Agent

**Equivalence:** Gluma One Bond, Optibond Solo Plus, Optibond Solo Plus 2, Clearfil SE Bond, Touch&Bond.

**Description/Intended Use:** Single bottle, self-etching, self-priming, light-cured bonding system that contains 4-META. Does not require acid etching of tooth surfaces, and can be polymerized with any available light-cure device. For use as the adhesive agent for direct or indirect restorations, and can be used as a sealant/desensitizer to minimize post-operative sensitivity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2002

Dr. Nelson J. Gendusa
Director of Research
Parkell, Incorporation
155 Schmitt Boulevard
Farmingdale, New York 11735

Re: K020239
Trade/Device Name: Touch&Bond-Plus
Regulation Number: 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: January 18, 2002
Received: January 23, 2002

Dear Dr. Gendusa:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/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): K020239

Device Name: TOUCH&BOND-PLUS

Indications for Use: This material is indicated for the following:

1. A dentin bonding agent used with direct filling materials that include but may not be limited to, composite resins, resin modified glass ionomers or compomers, etc.

2. A dentin bonding agent used with resin cements or composite luting agents to retain indirect tooth-colored a cast alloy restorations that include but may not be limited to indirect composite or porcelain inlays and onlays, laminate veneers, either resin or porcelain, porcelain-fused-to-metal crowns, etc.

3. Treatment of hypersensitive areas of exposed root surfaces.

4. A cavity sealant and desensitizer applied to exposed dentin that has been prepared to receive a laboratory fabricated restoration such as porcelain-fused-to-metal crowns, cast alloy or tooth-colored inlays or onlays, veneers, etc.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020239