K994302

FEB 7 2000

parkell

510(k) SUMMARY

Submitter:

Parkell, Inc.
155 Schmitt Blvd.
Box 376
Farmingdale, NY 11735
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Contact:

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

Submission Date: 14 December 1999

Trade Name: Currently Not Available

Common Name: Dentin Bonding System

Classification Name: Resin Tooth Bonding Agent

Equivalence: Gluma One Bond, Clearfil SE Bond, Optibond Solo, et al.

Description/Intended Use: **"TO BE NAMED"** may be described as a single-bottle, light cured, dentin-bonding system especially formulated for use with resin composite restorative materials. The material is self-etching and does not require acid etching of tooth surfaces. It will also reliably bond to properly prepared porcelain or alloy surfaces that are free of contamination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 7 2000

Mr. Nelson J Gendusa, D.D.S.
Director of Research
Parkell, Incorporated
155 Schmitt Boulevard
Farmingdale, NY 11735

Re: K994302
Trade Name: PARKELL RESIN TOOTH BONDING AGENT
Regulatory Class: II
Product Code: KLE
Dated: December 17, 1999
Received: December 21, 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.

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

K994302

510(k) Number (if known): K994302

Device Name: "TO BE NAMED"

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 restorations that include but may not be limited to indirect composite or porcelain inlays and onlays, lamin veneers, either resin or porcelain, etc.

3. Treatment of hypersensitive areas of exposed root surfaces.

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

— PRESCRIPTION DEVICE

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994302