K972421

510(k) SUMMARY

AUG 29 1997

Submitted By:	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:	23 June 1997
Trade Name:	EASY BOND
Common Name:	Dentin Bonding System
Classification Name:	Tooth Bonding Agent
Equivalence:	Prime & Bond 2.1, Clearfil Liner Bond 2, Optibond, Syntac
Description/Intended Use:	EASY BOND may be described as a single-bottle, light-cured, dentin bonding system especially formulated for use with resin composite restorative materials. It will also create reliable bonds properly prepared metallic surfaces that are free from contamination. EASY BOND is recommended on moist dentin substrates that have had any smear layer removed.

The above-cited material contains ingredients that are common in dental resins and bonding agents, and pose no health hazard when used according to directions. Use of resinous materials may be contra-indicated in persons with known acrylate and/or methacrylate allergies and/or hypersensitivities. The material herein described is polymerizable with currently available visible light curing devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG 29 1997

Re: K972421
Trade Name: Easy Bond
Regulatory Class: II
Product Code: KLE
Dated: June 23, 1997
Received: June 24, 1997

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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): K972421

Device Name: **EASY BOND**

Indications For Use:

For use as a tooth-bonding agent that seals patent dentinal tubules to reduce hypersensitivity and aids in the retention of tooth-colored dental restoratives when these are placed over EASY BOND that has been painted onto prepared cavities.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972421

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)