JUL 11 2003

K031212

510(k) SUMMARY

Submitter:

Parkell, Inc.
155 Schmitt Blvd.
Box 376
Farmingdale, NY 11735
TEL: 631-249-1134
FAX: 631-249-1242

Contact:

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

Submission Date: 15 April 2003

Trade Name: Currently Not Available

Common Name: Temporary Cement

Classification Name: Cement, Dental (other than zinc oxide-eugenol)

Equivalence: TempBond Clear, Sensitemp, GC Temporary Cement.

Description/Intended Use: A radiopaque, self-cure, resin-based temporary cement that is used to lute provisional restorations such as crowns, inlays, onlays, fixed bridges, laminate veneers, etc. or to temporarily cement permanent dental restorations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2003

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

Re: K031212
Trade/Device Name: Temporary Resin Cement
Regulation Number: 21 CFR 872.3275(b)
Regulation Name: Dental Cement
Regulatory Class: II
Product Codes: EMA
Dated: April 15, 2003
Received: April 17, 2003

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), 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) you may obtain. 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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031212

Device Name: TEMPORARY RESIN CEMENT (12-9-1/2)

Indications for Use: A resin-based cement designed for use with provisional restorations such as crowns, inlays, onlays, fixed bridges, etc. or for temporary cementation of permanent restorations.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031212