MAY 21 1999

K991270

510(k) SUMMARY

Submitter:

Parkell Products Inc.
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Contact:

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

Submission Date: 09 April 1999

Trade Name: SmarTemp

Common Name: TEMPORARY C&B RESIN

Classification Name: TEMPORARY CROWN & BRIDGE RESIN (CFR §872.3770)

Equivalence: LUXATEMP, PROVIPONT, PROTEMP GARANT, PROV-KB and 3M QUIKPLUS.

Description/Intended Use: Parkell's temporary C&B resin is a composite material intended for use as in the fabrication of provisional restorations for teeth prepared to receive crowns or bridges until final restorations for these teeth are completed. It is supplied in 50ml AutoMix Cartridges that automatically mix and dispense the proper ratio of base and catalyst (i.e., 1:1). The material is self-curing and sets with minimal heat and shrinkage. SmarTemp features a "rubbery" stage that permits easy trimming with scissors prior to final polymerization. SmarTemp has good physical properties and is suitable for long-term and long-span temporary restorations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 1999

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

Re: K991270
Trade Name: SmarTemp
Regulatory Class: II
Product Code: EBG
Dated: April 9, 1999
Received: April 13, 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

K991270

510(k Number (if known): K991270

Device Name: SMARTEMP TEMPORARY C&B RESIN

Indications for Use: For making temporary prostheses, such as crowns or bridges, for use until permanent restorations can be fabricated.

Prescription Use ✓
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991270