K974865

parkell

MAR 16 1998

510(k) SUMMARY

Submitter:

Parkell Products Inc.
155 Schmitt Blvd.
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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: 24 December 1997

Trade Name: CSR

Common Name: Denture Reline Material, Soft

Classification Name: Resin, Denture, Relining, Repairing, Rebasing (§872.3760)

Equivalence: Resil, Acusoft Soft Liner, Liteline VLC Soft Denture Reline, Permaflex Permanent Soft Denture Reliner, Soft Denture Reline Material Elastoline, Tokuyama Soft Relining

Description/Intended Use: Parkell's CSR is a self-curing (auto-polymerizing) silicone material that is intended for use by trained and licensed dental professionals as an easy-to-use soft reline material for removable prosthetic appliances, either full or partial, to enhance their fit and comfort. The cured silicone material is affixed to the tissue contacting surfaces of said prosthetic appliances and adheres thereto via the supplied adhesive which is simply applied with a brush. After adhesive application, the CSR silicone is expressed by means of a commonly available impression gun which causes the material to mix within an attached tip so that applied CSR is fully and completely mixed immediately upon its application to the tissue contacting surfaces of a removable prosthetic appliance. Mixed and polymerized CSR remains soft and adherent to tissue contacting over significant periods of time. The adherent silicone is akin to currently available addition-reaction silicone impression materials. The soft reline material is supplied in 50ml cartridges designed for use with impression guns, and kits also include a coating agent or glaze and adhesive necessary to cause a bond between the denture surfaces and the applied silicone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 1998

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

Re: K974865
Trade Name: CSR
Regulatory Class: II
Product Code: EBI
Dated: December 19, 1997
Received: December 29, 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 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,

Patricia Cascante for

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): K974865

Device Name: CSR

Indications for Use: A soft reline material for use by trained dental professionals. The material is a self-polymerizing material that is used to reline the tissue contacting resin surfaces of removable prostheses, either full or partial, to enhance the comfort and fit of said removable prosthetic appliances.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974865

Prescription Use ✓
(Per 21 CFR 801.109)