K053516

JAN 26 2006

510(k) SUMMARY

Submitter:

Parkell, 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: 13 December 2005

Trade Name: MucoHard

Common Name: Hard Denture Reline Resin

Classification Name: Resin, Denture, Relining, Repairing, Rebasing

Equivalence: Hard Reline, Ufi G Hard C, Rebase II, Secure Reline

Description/Intended Use:

This device is described as a chemically cured, hard setting, resin material intended to be used for relining, rebasing and/or repairing acrylic removable prostheses. It is delivered from a cartridge system via an impression gun found in the typical dental office. It is used in conjunction with a primer liquid that is applied to a denture base, allowed to dry and then applied to the primed surface to which it permanently adheres. The chemically polymerized material cures with minimal heat so that it may be used intra-orally. The current device is essentially similar to predicate devices and functions in a similar manner and for the same uses as these, cited elsewhere in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2006

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

Re: K053516
Trade/Device Name: MucoHard
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: December 13, 2005
Received: December 16, 2005

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053516

Device Name:MucoHard
Indications for Use:

A chemical (self) cure resin for use as a hard reline, repair, or rebase material for removable prostheses.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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