

XI. SAFE MEDICAL DEVICES ACT OF 1990 SUMMARY OF SAFETY AND EFFECTIVENESS. Sept. 17, 1998. [Separate Pages]

I.* Submitter: Donald LeRoy, Roydent Dental Products, 1010 West Hamlin Rd., Rochester Hills, MI, 48309, Phone: 248-652-2500.

II. Classification Names and numbers: Denture relining, repairing, rebasing resin, 76EBI

III. Common/Usual Name: Relining, rebasing resin.

IV. Proprietary Names: Mucoderm™ soft reliner system

V. Establishment Registration Number: 2523439

VI. Classification: Denture relining, rebasing resins were classified by the Dental Devices Panel into Class II. They are described under CFR 872.3760.

VII. Substantial Equivalence: Roydent™ is substantially equivalent to the classified device and those cleared for marketing by the 510(k) process under K964040, Trubyte Soft Reline System, Dentsply Int'l, K953589, Tokuyama Soft Relining, Tokuyama America; K963736, Soft Denture Rebasement Resin, Sybron Dental; K954810, Myerson IR Denture Base, Austenal, Inc.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, as a long-term resilient lining material for removable dentures, as the classified device and many cleared by the 510(k) process under K-964040 (Dentsply), K953589 (Tokuyama), K963736 (Sybron) and K954810 (Austenal).
2. The technological characteristics for this product are the same as those for the predicate devices and those currently on the market except for differences in methods of cure. The methods of cure of those equivalent products also vary widely including light-cured, heat-cured, and time-cured. Their composition also varies widely but has become fairly standard with acrylics or silicone polymeric substances.
3. Descriptive information provided shows that the materials from which Mucopren™ is made are substantially equivalent to (nearly identical with some) those of similar products, used for identical purposes, currently on the market.
4. The FDA "Decision-Making Process" chart was also used and appears in Appendix VI.
5. Test data for biocompatibility of Mucopren was supplied in accordance with ODE General Program Memorandum #G95-1, using International Standard ISO 10993 for surface devices having prolonged contact with mucosal membrane. Less formal biocompatibility tests from Europe also were made. These data are supplied in Appendix III.

A specific guidance document is not available for relining, rebasing resin materials. However, we followed the general outline, and applicable parts of the recent guidance document, "Dental Impression Materials--Premarket Notification," issued 8/17/98. We believe we have complied fully with guidance documents and usual practices in preparing premarket notifications. If additional information or explanation is needed, please call me at 248-652-2500 or fax me at 248-652-2505. Alternately, you may contact Dr. H. N. Dunning at 301-229-2138, 8309 Bryant Dr., Bethesda, MD 20817, who is acting on my behalf, for a local response.

Sincerely yours

A handwritten signature in cursive script, appearing to read "Don LeRoy".

Don LeRoy
President



NOV 13 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Don Leroy
President
ROYDENT Dental Products
1010 West Hamlin Road
Rochester Hills, Michigan 48309

Re: K983357
Trade Name: Mucopren™ Soft Relining System
Regulatory Class: II
Product Code: EBI
Dated: September 23, 1998
Received: September 24, 1998

Dear Mr. Leroy:

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.

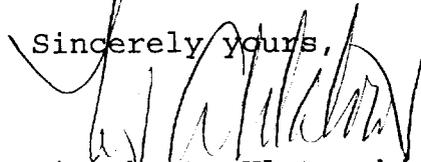
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

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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

K983357

VIII.1 Indications for Use: [Separate Page]

510(k) Number: NA

Device Name: Mucopren™ soft liner system

Intended for use as a long-term resilient lining material for removable dentures, to reline, repair, or rebase dentures.

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

Susan Puroer

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

510(k) Number K983357