

JUN 16 1998

SYBRON

DENTAL SPECIALTIES, INC.

K981448

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7425 - Phone
(714) 516-7488 - Facsimile
Wendy A. Urtel - Contact Person

Date Summary Prepared: April 1998

Device Name:

- Trade Name - Kerr Hard Denture Reline Material
- Common Name - Hard Denture Reline Material
- Classification Name - Denture Relining, Repairing or Rebasing Resin
21 CFR § 872.3760

Device for Which Substantial Equivalence is Claimed:

- *Kooliner*, GC America

Device Description:

The device is a paste/paste methacrylate based system for restoring function, comfort and esthetics to ill-fitting dentures. The system can be used either in the dental office or in the dental laboratory for relining of dentures.

Intended Use of the Device:

The intended use of Kerr Hard Denture Reline Material is for the restoration of function and form in dentures which have become ill-fitting due to alveolar bone loss over a period of time.

Substantial Equivalence:

The hard denture reline material is substantially equivalent to other legally marketed devices in the United States. The hard denture reline material marketed by GC America functions in a manner similar to and is intended for the same use as the product manufactured by Kerr Corporation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 1998

Ms. Wendy A. Urtel
Regulatory Affairs Specialist
Sybron Dental Specialties, Incorporated
1717 W. Collins Avenue
Orange, California 92667

Re: K981448
Trade Name: Kerr Hard Denture Reline Material
Regulatory Class: II
Product Code: EBI
Dated: April 17, 1997
Received: April 22, 1998

Dear Ms. Urtel:

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.

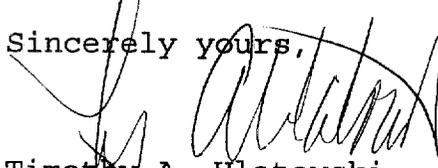
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Ms. Urtel

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

K 981448

Section I - Indications for Use

510(k) Number:

K 981448

Device Name: Kerr Hard Denture Reline Material

Indications for Use:

Kerr Hard Denture Reline Material is intended for the restoration of function and form in dentures which have become ill-fitting due to alveolar bone loss over a period of time.



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

510(k) Number K 981448