K99/425

JUN 15 1999

510(K) Summary

Date: June 7, 1999

Address: Heraeus Kulzer, Inc.
4315 S. Lafayette Blvd.
South Bend, IN.

Contact: Cheryl V. Zimmerman
219-299-6662

Device: Xantopren Comfort Base
Xantopren Activator

Substantially Equivalent to:
CutterSil Light **[K760756]**
CutterSil Mucosa **[K910165]**
CutterSil Universal Hardener (Paste & Liquid) **[K760756]**

Device Description:

Xantopren Comfort is a is silicone based condensation curing impression material used for all inlay, crown and bridge, edentulous and partial impressions. The advantage of Xantopren Comfort Light and Xantopren Comfort Medium is that the product is available in a cartridge delivery system that ensures that the correct amount of base and catalyst is used each time. With the cartridge delivery system a homogenous mix is obtained each time the material is expressed through the mixing tip. The user cannot manipulate the properties of the product because of the delivery system.

An evaluation of the clinical handling characteristics was evaluated for:

- dispensing of material(s)
- viscosity for application
- working time
- setting time
- color differentiation
- quality of impression
- ease of disinfection.

The putty material was used in conjunction with the low viscosity and the medium viscosity Xantopren. A minimum of 20 impressions were taken. Dispensing of the putty material is easily accomplished. One measuring scoop provides adequate material for either a bite or quadrant impression tray. Two measuring scoops are sufficient for a full

arch impression tray. After bleeding the cartridge, the low and medium Xantopren visciosities flowed well and were easily extruded through the mixing tip with no difficulty. The low and medium viscosity Xantopren were determined to be quite good for impressions. Both viscoisties flow well around the tooth preparation and into the sulcus. The working time and setting time was determined to be adequate, within the ranges stated in the instructions and similar to comparable impression materials.. Color differentiation between the low and medium viscosities and the putty's received an excellent rating. The quality of the impression is very good. And both Xantopren Light and Medium bond well to currently marketed products CutterSil Putty Plus and CutterSil Comfort.

The injection tips on the cartridge delivery system can be angled to suit the needs to the dentist. Pouring of the impression is compatible with silicone products (condensation or addition) that are currently in the market place. Ease of disinfection is consistent with similar materials, and no distortion was observed after disinfection.

Product Comparison:

PROPERTIES	Xantopren Comfort Light	CutterSil Light
Mixing Time (s)	-	30
Working Time (min)	2:00	2:00
Setting Time (min)	3:00	4:00
Shore A Hardness	36	-
Max. Deformation Under Pressure (%)	8.0	2-10
Recovery From Deformation (%)	>98	97.5
Linear Dimensional Change (%)	1.0	-1.0 - 0

PROPERTIES	Xantopren Comfort Medium	CutterSil Medium
Mixing Time	-	45
Working Time	2:30	2:00
Setting Time	3:30	4:00
Shore A Hardness	38	-
Max. Deformation Under Pressure	7.5	2-10%
Recovery From Deformation	>98	97.5
Linear Dimensional Change	1.0	-1.0 -0

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 1999

Ms. Cheryl V. Zimmerman
Quality Operations and Regulatory Affairs
Heraeus Kulzer, Incorporated
4315 South Lafayette Boulevard
South Bend, Indiana 46614-2517

Re: K991425
Trade Name: Xantopen® Comfort
Regulatory Class: II
Product Code: ELW
Dated: April 21, 1999
Received: April 23, 1999

Dear Ms. Zimmerman:

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

K991425

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510(k) Number (if Known): K991425

Device Name: Xantropren Comfort Base Paste and Activator

Indications For Use:

Xantropren Comfort is a silicone based condensation curing impression material used for all inlay, crown and bridge, edentulous and partial impressions. The Xantropren Comfort Activator is the catalyst. This product is packaged in a cartridge delivery system which will dispense equal amounts of base and activator.

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

Concurrence of CDRH, Office of Device evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Susan Runner (Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K991425