3/3/99

K990306

510K
SUMMARY

Date Prepared 01/28/99

Submitted by Clark Smith D.M.D.

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Prepared by
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Contact Clark Smith D.M.D.

Trade name - Hydro-Cast Dental Etching Gel

Common name - Dental Etching Gel

Classification Name - Sealant, Pit, and Fissure, and Conditioner (872.3765)

Substantial equivalence claimed to - Orthosource Etch Systems, 872.3765, K861245

Description of the device.
The Hydro-Cast Etching Gel is a 35% phosphoric acid solution. It can be applied with a micro-brush, syringe, or pipette.

Intended use of device.
Hydro-Cast Etching Gel is used to prepare the surface of the tooth before a dental adhesive is used. It is applied directly on the tooth, and after fifteen seconds, the tooth is rinsed and dried.

TECHNOLOGICAL CHARACTERISIC COMPARISON

Orthosource Etch Systems	Hydro-Cast Etching Gel
Mixture of phosphoric acid, water, coloring agents, xanthan gum.	Preparation of phosphoric acid, reagent grade water, FD&C coloring agents, xanthan gum.

Summary: The technological characteristics of the two devices are identical.

DISCUSSION
NON-CLINICAL PERFORMANCE TESTING AND DATA

The testing of Hydro-Cast Dental Etching Gel was conducted using five random subgroups with three samples drawn from each. Etching gel from each sample was placed on an enamel surface. After fifteen seconds, a single component adhesive was applied to each sample. The adhesive cured well, and the bond strength desired was attained.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 1999

Clark Smith, D.M.D.
Executive Vice President
Kay-See Dental Manufacturing Company
124 East Missouri Avenue
Kansas City, Missouri 64106-1294

Re: K990306
Trade Name: Hydro-Cast Dental Etching Gel. Model 60025
Regulatory Class: II
Product Code: EBC
Dated: January 29, 1999
Received: February 1, 1999

Dear Dr. Smith

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

STATEMENT OF INDICATIONS FOR USE

Hydro-Cast Dental Etching Gel is used to prepare the tooth surface before a dental adhesive is used. It is applied directly on the tooth surface, the area is rinsed and dried after fifteen seconds, and then tooth surface is ready for the adhesive.

Clark Smith D.M.D

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990306

Prescription Use _____
(Per 21 CFR 801.109)