FEB 1 2006

K053103

ABBREVIATED 510 (K) SUMMARY

As Required by the Safe Medical Devices Act of 1990

Apex Dental Materials, Inc.
23329 Mallard Court
Deer Park, IL. 60010
Tele- (877) 273-9123

510 (K) Submission Date: November 3, 2005

Contact Person: Chris Kulton

Device Name:

Trade Name:	**Interface™**
Common Name:	Dental Bonding Adhesive
Classification Name:	Resin Tooth Bonding Agent, per 21 CFR parts 872.3200

Classification:

Regulatory Class:	II
Product Code:	KLE

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE

PREDICATE DEVICE

Raw silane (3-(Trimethoxysily)propyl methacrylate, 98%) hydrolyzed with acetic acid is an industry standard priming agent that is applied to prime ceramic surfaces pre-etched with hydrofluoric acid. This system combination is used to prepare inorganic ceramic surfaces prior to bonding with an organic resin based adhesive or cement. Historically hydrolyzed silane has been used to increase bonding strength, by acting as a coupling agent between the inorganic ceramic surface and the organic resin based restorative material. This basic coupling agent chemistry is only used to prime ceramics prior to bonding with an adhesive or cement. When

Continued:

repairing ceramic restorations involving tooth structure, this system does not have the capability to prime or condition exposed tooth substrate. This must be performed in a separate application protocol involving tooth etching conditioners such as a phosphoric acid gel.

DESCRIPTION OF APPLICATION DEVICE

Interface™ is a ceramic primer which allows the clinician to bond any type of ceramic to a tooth substrate without the pre-application of hydrofluoric acid. **Interface™** is prepared by mixing one drop of each component and then waiting 30 seconds for the materials to co-mix. The advantage of being able to mix these chemistries just prior to use, assures the clinician that the mixture is always fresh. Since both chemistries are separate prior to mixing the shelf life of the materials is very stable. In comparison, traditional hydrolyzed silane has an extremely short shelf life which can unknowingly jeopardize bond strengths once near expiration or expired.

Interface™ can be used to prime/ condition tooth structure prior to repairing a tooth to ceramic restoration. The need to acid etch the substrates prior to bonding with either phosphoric or hydrofluoric acids is not necessary. As a result this eliminates any confusion for the clinician on how to prep the restoration for successful bonding.

Interface™ can be used to bond to ceramic, dentin and enamel all at the same time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2006

Mr. Chris Kulton
Co-Owner
Apex Dental Materials, Incorporated
23329 Mallard Court
Deer Park, Illinois 60010

Re: K053103
Trade/Device Name: Interface™
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: November 05, 2005
Received: January 11, 2006

Dear Mr. Kulton:

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): K053103

Device name: **Interface™**

Indications For Use:

Interface ™ is a ceramic primer/ conditioner, which allows the clinician to bond any type of ceramic (including newer high strength ceramic materials) to a tooth substrate. **Interface** ™ when used in conjunction with a resin adhesive can be used for ceramic and ceramic to tooth repairs, as well as bonding ceramic inlays, onlays, crowns and veneers.

Interface ™ is to be used as a ceramic primer/ conditioner allowing bonding to ceramic, dentin and enamel all at the same time. With **Interface** ™, any dental ceramic can be repaired safely in the mouth without the use of dangerous hydrofluoric acid.

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

Concurrence of CDRL, Office of Device Evaluation (ODE)

Prescription use X
(Per 21 CFR 801.109

OR

Over- The- Counter Use

(Optional Format 1-2-96)

K053103