APR 2 4 2002 K020570

510 (K) SUMMARY

As Required by the Safe Medical Devices Act of 1990

Apex Dental Materials, Inc.
603 Berkley Court
Schaumburg, IL. 60194
Phone: (847) 490-1014

510 (K) Submission Date: February 20, 2002

Contact Person: Chris Kulton

Device Name:

Trade Name:	SIMPLICITY™
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

ECLIPTOMER (Bisco, Inc.) is a universal dental adhesive system that is designed to bond composite to dentin, enamel, cast metals, treated porcelain and set amalgam. This system is also designed for indirect techniques as well as amalgam bonding.

ECLIPTOMER (Bisco, Inc.) is an acetone based primer that is dependent on a clean etched dentin/enamel surface that is visibly moist. Its physical properties are similar to the applicant device and uses are identical. Like the applicant device, ECLIPTOMER is one component used in conjunction with a complete dental bonding system. It hardens by a light cure polymerization mechanism employing a light initiator, and a chemical activator.

Summary continued:

DESCRIPTION OF APPLICATION DEVICE

SIMPLICITY™ is a light cured (free radical polymerization), self-etching dental adhesive system, designed to provide a dentist with an increased ease of use that is less technique sensitive. The bonding system combines both the etchant and primer applications into one simple step. Thus, allowing for more predictable clinical results without sacrificing bond strength integrity.

SIMPLICITY™ 2 is an acetone based adhesive that is dependent on the prepared surface of its conditioner (SIMPLICITY™ 1). This acidic conditioner application is a procedure that is very similar to the phosphoric acid etching process of dentin/enamel substrate in the ECLIPTOMER system. Applying the SIMPLICITY™ 2 (adhesive resin) directly to the conditioner prepared surface, assures proper moistness on the bonding interface, resulting in a reliable simplified bonding protocol.

Summary continued:

INTENDED USES OF APPLICANT DEVICE

SIMPLICITY™ is a universal adhesive system that when properly employed, can be used to seal enamel/dentin prior to restoring with light cured or self cured composite materials. Also, in situations of indirect restorations, the bonding system can be used to seal a preparation when using a light cured, self cured or dual cured composite cement or glass ionomer or resin-modified glass ionomer cement. In addition, the system allows the dentist to bond a post and core, along with the use to treat hypersensitive and/or exposed root surfaces.

PERFORMANCE CHARACTERISTICS and CONCEPTS

SIMPLICITY™ has similar handling to the ECLIPTOMER (Bisco, Inc.) adhesive system. From the physical testing observations and analysis, including shear bond strength to dentin and enamel, we suggest that SIMPLICITY™ is substantially equivalent to ECLIPTOMER (Bisco, Inc.). Along with this we would suggest the individual components of SIMPLICITY™ are long time industry standards and are utilized in numerous dental bonding systems currently marketed in the United States (see Confidential Formulation Details on page 5).

Equivalent Product and Manufacturer	Corresponding 510(k) Numbers
ECLIPTOMER (Bisco, Inc.)	K945604

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2002

Mr. Chris Kulton
Apex Dental Materials, Incorporated
603 Berkley Court
Schaumburg, Illinois 60194

Re: K020570
Trade/Device Name: SIMPLICITY™
Regulation Number: 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: February 20, 2002
Received: February 21, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/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

Indications for Use

510(K) Number (if known):

Device name: SIMPLICITY™

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(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)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K060570