K092539

510 (K) Summary:

OCT - 1 2009

As Required by the Safe Medical Devices Act of 1990

Apex Dental Materials, Inc.
330 Telser Road
Lake Zurich, IL 60047
Phone: (877) 273-9123

510 (K) Submission Date: August 4th, 2009

Contact Person: Chris Kulton

Device Name:
Trade Name: Seamfree™
Common Name: Material, Tooth Shade, Resin
Classification Name: Tooth Shade Resin Material, per 21 CFR parts 872.3690

Classification:
Regulatory Class: 2
Product Code: EBF

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE

Bisco Sculpting Resin (Bisco, Inc. K030585) is a wetting material designed to reduce tackiness of composite materials and make delivery of composite materials easier and more consistent. The material is applied directly to dental instruments or materials to achieve this goal.

Bisco Sculpting Resin (Bisco, Inc. K030585) is a methylmethacrylate based composite material formulated to provide the user a method to ease the manipulation of restorative dental materials. Bisco Sculpting Resin is activated thru a free radical polymerization mechanism.

510 K Summary (continued):

DESCRIPTION OF APPLICATION DEVICE

Seamfree™ is a methylmethacrylate based resin material used as a lubricant for dental instruments and composites. The elimination of "tackiness" from dental materials makes the delivery and handling of dental composite materials faster and more consistent. Seamfree™ is activated via free radical polymerization. Seamfree is compatible with all methylmethacrylate based materials.

INTENDED USES OF APPLICANT DEVICE

Seamfree™ is intended to be used to lubricate restorative instruments and materials. It can be used in all dental restorations and with any methylmethacrylate based material.

510 K Summary (continued):

PERFORMANCE CHARACTERISTICS and CONCEPTS

Seamfree™ has similar performance to the Bisco Sculpting Resin (510K number K030585, Bisco, Inc.). From the testing observations and analysis, including film thickness, we suggest that Seamfree™ is substantially equivalent to Bisco Sculpting Resin (510K number K030585, Bisco, Inc.). Along with this, we would suggest the individual components of Seamfree™ are long-time industry standards and are utilized in numerous dental composite products currently marketed in the United States (see Confidential Formulation Details on page 5).

Equivalent Product and Manufacturer	Corresponding 510(k) Numbers
Bisco Sculting Resin (Bisco, Inc.)	K030585
Ultradent Composite Wetting Resin (Ultradent Products Inc.)	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Chris Kulton
Co-Owner
Apex Dental Materials, Incorporated
330 Telser Road
Lake Zurich, Illinois 60047

OCT - 1 2009

Re: K092539
Trade/Device Name: Seamfree™
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: August 4, 2009
Received: August 19, 2009

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For

Susan Runner, D.D.S., M.A.
Acting 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): K029539

Device Name: Seamfree™
Indications for Use:

Seamfree™ is intended to be used to lubricate restorative instruments and materials. It can be used in all dental restorations and with any methylmethacrylate based material.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR Part 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulloy for HSR

Division Sign-Off)
ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

510(k) Number: K092599