K072480

Pentron Clinical Technologies, LLC

Advancing dentistry one innovation at a time.™

NOV 2 1 2007

6.0 510(K) SUMMARY

Pentron Clinical Technologies, LLC.
68 North Plains Industrial Road
Wallingford, CT 06492
Tel: 203-265-7397
Fax: 203-284-4986
Contact: Greg Moreau

Trade Name:	Generation 8 SE Adhesive
Common Name:	Bonding Agent
Classification Name:	Agent, Tooth Bonding, Resin, 21CFR 872.3200, KLE

Generation 8 SE Adhesive product performs the same intended function as its predicate device, One Coat SE Bond (reference K033760) for direct bonding applications. Both devices are intended for direct bonding of composite materials to enamel or dentin as well as for adhesive bonding of other dental materials such as composite material to ceramics, composite material to composite material and composite material to metals and amalgam.

The subject device is a light-cured self-etching, self-priming adhesive in a solvent-free resin formulation. The Generation 8 SE Adhesive performs the etching/priming/bonding process as a single step once the restorative site has been properly prepared.

Device composition is approximately 40% filler by weight with filler particle size values less than 2 microns. As with other resin products manufactured by Pentron Clinical Technologies, LLC., the predominant filler for Generation 8 SE Adhesive is a barium boro-silicate glass. This filler type provides the subject device with the required strength and radiopacity features.

Product is supplied as refills in a variety of delivery systems; multi-use bottle or syringe as well as a single dose delivery system.

A review for safety and effectiveness was performed and found not to have been affected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2007

Mr. Greg Moreau
Quality Systems Manager
Pentron Clinical Technology, LLC
68 -70 North Plains Industrial Road
Wallingford, Connecticut 06492

Re: K072480
Trade/Device Name: Generation 8 SE Adhesive
Regulation Number: 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: August 28, 2007
Received: September 4, 2007

Dear Mr. Moreau:

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.

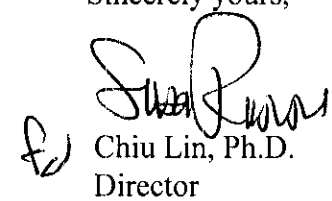
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (21CFR 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 Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.0 INDICATION FOR USE STATEMENT

510(k) NUMBER (IF KNOWN):

DEVICE NAME: **Generation 8 SE Adhesive**

INDICATION FOR USE:

Generation 8 SE Adhesive product is indicated for direct bonding of composite and compomer materials to enamel and dentin. Additionally, device use is appropriate for adhesive bonding of other dental materials, such as composite material to ceramics, composite material to composite material and composite material to metals and amalgam.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over –The-Counter-Use ____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(Division Sign-Off) Division Number: K072480