K072545

Pentron Clinical Technologies, LLC

Advancing dentistry one innovation at a time!™

OCT 26 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:	Artiste SE Flowable Composite
Common Name:	Bonding Agent
Classification Name:	Material, Tooth Shade, Resin, 21CFR 872.3690, EBF

Artiste SE Flowable Composite product, as a suitable dental restorative material, performs similar intended functions as its predicate device, Embrace Wet-Bond Restorative Materials (reference K031877). Both devices are intended to provide the dental clinician a safe and effective method to repair dentition using a variety of technique applications. Applications include:

- Self-etch base liner
- Restorations of carious lesions
- Class 1, III, and V cavity preparations
- Pit and fissure sealant.

The subject device is a light-cured self-etching, self-adhesive composite in a BisGMA-free resin formulation. The Artiste SE Flowable Composite requires no application of etchant, primer or adhesive prior to device use once the restorative site has been properly prepared.

Device composition is approximately 65% 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 Artiste SE Flowable Composite is a barium boro-silicate glass. This filler type provides the subject device with the required strength and radiopacity features.

Product is supplied in various shades either in multi-use syringe or single dose delivery systems. Product packaging includes kit or refill configuration.

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

OCT 26 2007

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

Re: K072545
Trade/Device Name: Artiste SE Flowable Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: September 6, 2007
Received: September 10, 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.

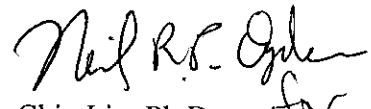
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K072545

DEVICE NAME: **Artiste SE Flowable Composite**

INDICATION FOR USE:

Artiste SE Flowable Composite product is a self-etch, self-adhesive flowable resin composite indicated for light-cured dental restorations. Applications include:

- Self-etch base liner
- Restorations of carious lesions
- Class 1, III, and V cavity preparations
- Pit and fissure sealant.

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

510(k) Number: K072545

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over –The-Counter-Use** ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)