## 510(k) Summary

NOV 17 2010

**Trade Name:** **SA Flowable Composite**

**Date Prepared:** August 31, 2010

**Sponsor:** DMG USA, Inc.
23 Frank Mossberg Drive
Attleboro, MA 02703
Owner/Operator No. 9005969

**Device Generic Name:** Tooth Shade Resin Material

**Classification:** According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

**Regulation:** 21 CFR 872.3690; Product Code EBF

**Indications for Use:**

SA Flowable Composite is a self-adhesive, light-curing, flowable composite. SA Flowable Composite applications include:
- Minor restorations of class I (without contact point)
- Underfillings of classes I and II
- Fissure sealing
- Repairs of composite restorations
- Modifications to temporaries and long-term temporaries
- Blocking out and filling of undercuts

**Device Description:**
SA Flowable Composite is a self-adhesive, light-curing, flowable composite with optimum consistency for the described indications. The radiopaque composite is immediately ready for use because the preparatory steps of etching, priming and bonding are unnecessary. The SA Flowable Composite will be supplied in convenient applicators.

**Predicate Device:**
The SA Flowable Composite is substantially equivalent to the currently marketed Pentron Artiste SE Flowable Composite product cleared in K072545.

**Safety and Performance:**
SA Flowable Composite is a tooth shade resin material that complies with the requirements described in ISO 7405:2008 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry and in ISO 4049:2009 Dentistry – Polymer-based filling, restorative and luting materials. Performance testing has been performed in accordance with ISO 4049:2009 to demonstrate that the SA Flowable Composite is equivalent to or better than the predicate devices in terms of several material properties including film thickness, depth of cure, flexural strength, water sorption and solubility.

**Conclusion:**
Based on the indications for use, technological characteristics, and comparison to the predicate device, the SA Flowable Composite has been shown to be substantially equivalent to its predicate devices, and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DMG USA, Incorporated
C/O Ms. Pamela Papineau
Regulatory Affairs Consultant
Delphi Medical Device Consulting
5 Whitcomb Avenue
Ayer, Massachusetts 01432

NOV 17 2010

Re: K102603
Trade/Device Name: SA Flowable Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Codes: EBF and EBC
Dated: August 31, 2010
Received: September 10, 2010

Dear Ms. Papineau:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K102603

Device Name: **SA Flowable Composite**

NOV 17 2010

**Product Indications for Use:**

SA Flowable Composite is a self-etching, self-adhesive, light-curing, flowable composite.

SA Flowable Composite applications include:

- Minor restorations of class I (without contact point)
- Underfillings of classes I and II
- Fissure sealing
- Repairs of composite restorations
- Modifications to temporaries and long-term temporaries
- Blocking out and filling of undercuts

Prescription Use X OR Over-the -Counter Use ____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K102603