



Food and Drug Administration  
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Silver Spring, MD 20993-0002

September 21, 2015

Danville Materials LLC  
Dong Hua  
Regulatory Affair Director  
3420 Fostoria Way Suite A-200  
San Ramon, California 94583

Re: K151514  
Trade/Device Name: Prestige  
Regulation Number: 21 CFR 872.3690  
Regulation Name: Tooth Shade Resin Material  
Regulatory Class: Class II  
Product Code: EBF  
Dated: June 18, 2015  
Received: June 23, 2015

Dear Dong Hua:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

A handwritten signature in black ink that reads "Susan R. Keith, DDS, MA". The signature is written in a cursive style and is positioned over a faint, semi-transparent watermark of the FDA logo.

Erin Keith  
Director  
Division of Anesthesiology,  
General Hospital, Respiratory, Infection  
Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

Device Name

Prestige

Indications for Use (Describe)

Prestige is a dental composite restorative material designed to be used in all classes of cavities

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*



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## 007\_ 510(K) Summary

This summary of the Traditional 510(K) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92

### A. Applicant's Name and Address

- Name: Danville Materials LLC
- Address: 3420 Fostoria Way Suite A-200  
San Roman, CA 94583  
USA
- Contact Person: Dong Hua
- Title: Regulatory Affair Director and QA Manager
- Phone: 800-827-7940/925-973-0710. Ext. 212
- Fax: 925-973-0764
- Date Summary Prepared: May 26, 2015

### B. The Name of the Device:

- Trade/Proprietary Name: Prestige™
- The common name of the device: Tooth Shade Resin Material
- The Classification Name: Material, Tooth Shade, Resin per 21 CFR 872.3690
- Product Code EBF has been classified as a Class II device

### C. Legally Marketed Predicate Device to Which Substantial Equivalence (SE) is claimed:

- **K943642** Herculite XR & XRV By Sybron Dental Specialties, Inc

### D. Description of the Device:

- Indication For Use: Indication For Use: Prestige™ is a dental composite restorative material designed to be used in all classes of cavities
- Intended Use of the Device: Prestige™ is a light-cured, Nanohybrid dental restorative material intended for use for the restoration in all classes of cavities

### E. A comparison between the Herculite XR & XRV by Sybron Dental Specialties, Inc and Prestige™ by Danville Materials to determine SE:

- The equivalence to the predicate device is supported by the Physical and Mechanical Properties performance testing
- Chemicals, function of each component of the product are identified
- Similarities in the Indications for Use:

Product	510(K) Number	Classification Name	Indications For Use
Herculite XR & XRV By Sybron Dental Specialties, Inc	K943642	Tooth Shade Resin Material	dental composite restorative material designed to be used in all classes of cavities
Prestige™	New	Tooth Shade Resin Material	Prestige™ is a dental composite restorative material designed to be used in all classes of cavities

➤ Discussion of Non-Clinical and Clinical tests performed for determination of Substantial Equivalence:

Prestige™ is a resin based material that is light cured, the same as used by our predicates, Herculite XR & XRV By Sybron Dental Specialties, Inc (K943642). These materials have been widely used by numerous manufacturers in the medical/dental industry.

Non-Clinical Testing performed on Prestige™ included the followings:

- Flexural Strength
- Depth of Cure
- Sensitivity to Ambient Light
- Diametral Strength
- Water Sorption
- Shade and Color Stability
- Radiopacity

The substantial equivalence or suitability to the intended purpose of Prestige™ has been demonstrated by a combination of in-house testing and side-by-side comparisons to predicate devices currently on the market. Results of our bench testing indicate that Prestige™ has the same performance and technological characteristics.

Summary of the differences between the subject and the predicate devices

Three main differences between Prestige™ and Herculite XR & XRV are:

- Increased radiopacity
- Different initiating
- Decreased film thickness

**F. Conclusion:**

Our records indicate that our predicates have been used by dentists and large group practices in the United States and purchased by a large number of international distributors.

In conclusion, the differences between the subject device and the predicate device do not affect substantial equivalence, or raise different questions of substantial



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equivalence. The subject device, Prestige™ has been designed and manufactured with the intended use and claims for the product in mind. Prestige™ is substantially equivalent to the predicate device and may be released to the market.