DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

March 18, 2015

Danville Materials, LLC.
Ms. Dong Hua
Regulatory Affairs Director and QA Manager
3420 Fostoria Way, Suite A200
San Ramon, California 94583

Re: K142886
Trade/Device Name: DMRC Self-cure Bracket Adhesive One Step and Primer
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: Class II
Product Code: DYH
Dated: February 18, 2015
Received: February 20, 2015

Dear Ms. 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142886

Device Name

DMRC Self-Cure Bracket Adhesive One Step and Primer

Indications for Use *(Describe)*

This device is a one step no-mix adhesive for direct bonding of orthodontic bracket to tooth structure

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.

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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: March 9, 2015

B. **The Name of the Device**:

- Trade/Proprietary Name: DMRC Self-Cure Bracket Adhesive One Step and Primer
- The common name of the device: Dental adhesive, bracket and tooth conditioner, Resin
- The Classification Name: Bracket adhesive resin and tooth conditioner per 21 CFR 872.3750, product Code DYH has been classified under section 513 of the Act as a Class II device

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

- **K941015** ORMCO SYSTEM 1+ (TM) By ORMCO CORP

D. **Description of the Device**:

The DMRC Self-Cure Bracket Adhesive One Step and Primer is a resin based adhesive designed for direct bonding of orthodontic brackets with no-mix step. This product can be used for patients of all ages.

E. **Indication For Use**:

The DMRC Self-Cure Bracket Adhesive One Step and Primer is a one step, no mix adhesive for direct bonding of orthodontic bracket to tooth structure

F. A comparison of the **ORMCO SYSTEM 1+ (TM) by ORMCO CORP** and the **DMRC Self-Cure Bracket Adhesive One Step and Primer** to determine **SE**:

- The equivalence to the predicate device is supported by the physical performance

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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
ORMCO SYSTEM 1+ (TM)	K941015	Adhesive, Bracket and Tooth Conditioner, Resin	Self-Cure orthodontic bracket adhesive used with a liquid primer and enamel etching gel to adhere orthodontic brackets to tooth surfaces
DMRC Self-Cure Bracket Adhesive One Step and Primer	New (K142886)	Adhesive, Bracket and Tooth Conditioner, Resin	A one step no-mix adhesive for direct bonding of orthodontic bracket to tooth structure

- Discussion of Non-Clinical and Clinical Tests performed for Determination of Substantial Equivalence:

The DMRC Self-Cure Bracket Adhesive One Step and Primer is a resin based adhesive designed for direct bonding of orthodontic brackets with no-mix step. The materials used in The DMRC Self-Cure Bracket Adhesive One Step and Primer are the same as used by our predicate, ORMCO SYSTEM 1+ (TM) By ORMCO CORP (K941015), which is the similar dental adhesive product. The raw chemical materials have been widely used by numerous manufacturers in the medical/dental industry.

Non-Clinical Testing performed on the DMRC Self-Cure Bracket Adhesive One Step and Primer included the following:

- Vicker's Hardness
- Shear Bond Strength on enamel (MPa)
- Self-Cure Set Time (Min)

There is no specific standard is used. Results of our bench testing indicate that DMRC Self-Cure Bracket Adhesive One Step and Primer was equivalent to the predicate device.

Test Method	DMRC Self-Cure Bracket Adhesive and Primer	System 1+ and Activator (Ormco)
Vicker's Hardness	37 (5)	29 (3)
Shear Bond Strength on enamel (MPa)	6.7 (1)	5.2 (0.7)
Self-Cure Set Time (min)	2:30	2:00

The subject device was determined to be substantial equivalent to the predicate in terms of biocompatibility, based on a risk assessment and the identification of legally marketed predicate devices for all ingredients in the chemical composition, as well as cytotoxicity testing

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of device extract performed according to ISO 10993-5, 2009 and ISO 10993-12, 2012. The device extract was found to be not cytotoxic.

G. **Conclusion**:

In conclusion, the subject device, the DMRC Self-Cure Bracket Adhesive One Step and Primer has been designed and manufactured with the intended use and claims for the product in mind. The bench testing contained in our submission demonstrates that there are no differences in their technological characteristics, thereby not raising any new issues of safety or effectiveness. The DMRC Self-Cure Bracket Adhesive One Step and Primer is as safe and effective as the predicate device, and may be released to the market.