



# U.S. Department of Health & Human Services

---

**Food and Drug Administration**

## SAVE REQUEST

**USER:** (kml)  
**FOLDER:** K142881 - 186 pages  
**COMPANY:** DANVILLE MATERIALS, LLC. (DANVMATELLC)  
**PRODUCT:** ADHESIVE, BRACKET AND TOOTH CONDITIONER, RESIN (DYH)  
**SUMMARY:** Product: DMRC DUAL CURE ORTHODONTIC BAND CEMENT

**DATE REQUESTED:** Mar 14, 2016

**DATE PRINTED:** Mar 14, 2016

**Note:** Printed



K142881

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HZ-401)  
1390 Piccard Drive  
Rockville, Maryland 20850

September 5, 2014

FDA/CDRH/DCC

OCT 02 2014

RECEIVED

Re: 510(k) Notification

Attention: Document Control Clerk

In accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in conformance with 21 CFR 807, this premarket notification is being submitted at least 90 days prior to the date when Danville Manufacturing dba Danville Engineering proposes to introduce into interstate commerce for commercial distribution a Dual Cure Orthodontic Band Cement to be known as Dual Cure Orthodontic Band Cement.

The following information is being submitted in conformance with 21 CFR 807.87:

**A. Device Name/Description:**

*Trade/Proprietary Name: DMRC Dual Cure Orthodontic Band Cement:*

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.

Device Description: This device is a two paste dual-cure adhesive intended for use as an *orthodontic band cement*.

**B. Establishment Registration Number: 2954330**

**C. Recognized Standards:**

ISO 4049 is the recognized consensus standard applicable to Polymer based filling and restorative materials. ADA Specification 27 is another recognized standard for Polymer based restorative materials. Since the composition of the DMRC Dual Cure Orthodontic Band Cement listed in Section A is the same as polymer based filling and restorative materials, ISO 4049 tests were performed. The specific tests performed were Flexural Strength in both Light Cure and Self Cure modes, Sensitivity to Ambient Light, Depth of Cure. Diametral Strength measurements were also carried out according to ADA Specification No. 27.

For adhesive tests such as Shear Bond Strength on Enamel, a proprietary test method was used similar to ISO 11405 which is the recognized consensus standard applicable to Dental Adhesives, see 012\_Danville Test Method B\_Ultradent Bracket Shear Bond Strength (SBS). Proprietary test methods were used for Set Time measurement, see 013\_Danville Test Method C\_WT/ST for Ortho Products and determination of Vicker's hardness, see 011\_Danville Test Method A\_Vicker's Hardness.

**D. Labeling:**

The Instructions, labeling and packaging for DMRC Dual Cure orthodontic Band Cement are enclosed in 008\_Proposed Labeling and IFU.

1-05  
24

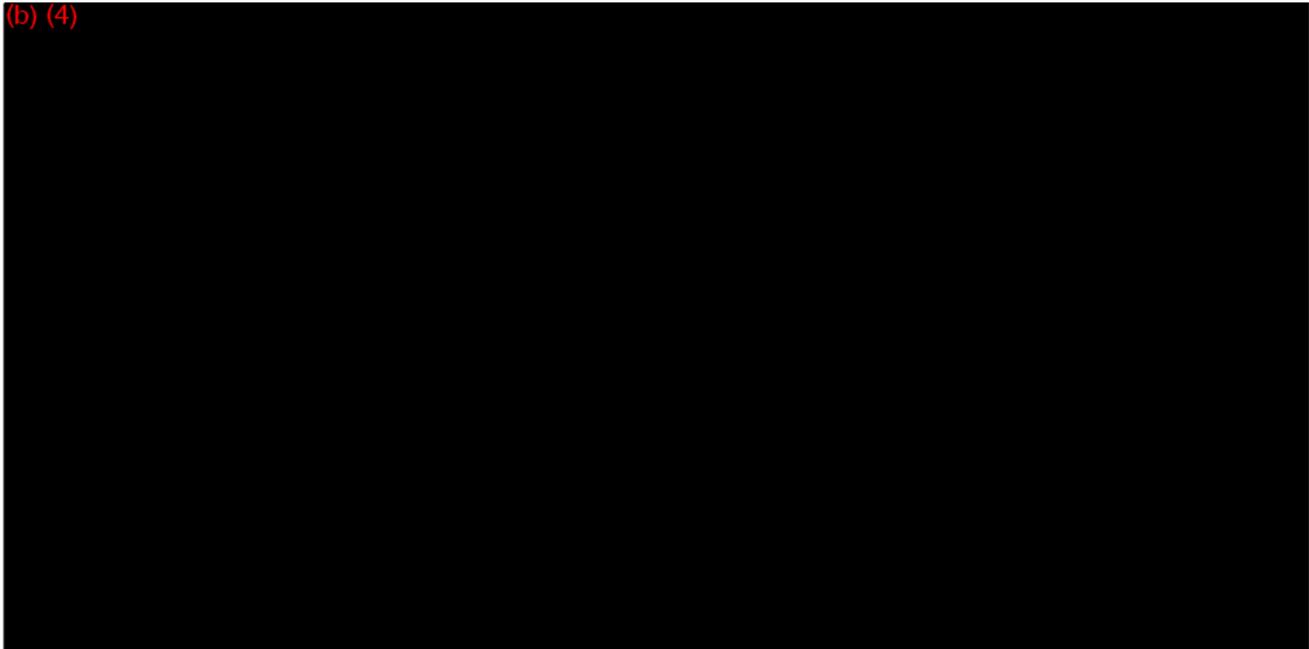
**E. Predicate Devices:**

DMRC Dual Cure Orthodontic Band Cement: Band Lok, marketed by Reliance Orthodontic Corp.

The equivalence of DMRC Dual Cure Orthodontic Band Cement to the predicate device is supported by **Table 2** and the enclosures following:

**Table 2. Physical Properties of DMRC Dual Cure Orthodontic Band Cement**

(b) (4)



The following materials for DMRC Dual Cure Orthodontic Band Cement are enclosed in the 004\_ Table of Contents\_ DMRC Dural Cure Orthodontic Band Cement:

1. Instruction Manual: 008\_ Proposed Labeling and IFU
2. Product Labeling: 008\_ Proposed Labeling and IFU
3. Premarket Notification Statement 21 CFR 807.93: 009\_ Premarket Notification Statement 21 CFR 807.93
4. Premarket Notification Truthful and Accurate Statement 21 CFR 807.87(k): 007\_ Truthful and Accurate Statement
5. Indications for Use Form: 005\_ Indications for Use Statement
6. Danville Test Method A: 011\_ Danville Test Method A\_ Vickier's Hardness
7. Danville Test Method B: 012\_ Danville Test Method B\_ Ultradent Bracket Shear Bond Strength (SBS)
8. Danville Test Method C: 013\_ Danville Test Method C\_ WT/ST for Ortho Products

**F. Chemical Identity:**

The name, function and CAS number of each component of this product is identified in **Table 4.**

**Table 4. Material Component Description**

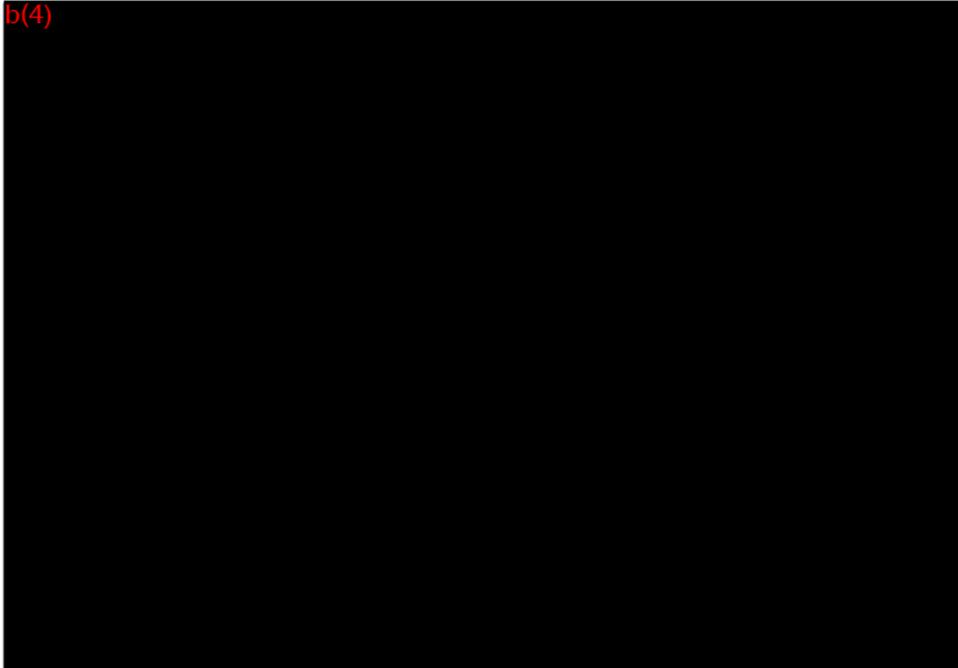
b(4)

Chemical raw materials are purchased from well established vendors, The MSDS sheets for the main chemical components and a diagram of the chemical structure and the molecular formula of the finished material are enclosed in 014\_Other (MSDS on raw chemical materials in major ingredients).

The complete formulation for this product, identifying the individual chemical components by percentage to a sum of 100% are attached in **Table 5**.

**Table 5.** Composition of Orthodontic Adhesives and Band Cement

b(4)



**G. Physical and Mechanical Properties**

The Physical Properties of the product is shown in the Tables 2.

**Table 2.** Physical Properties of DMRC Dual Cure Orthodontic Band Cement

(b) (4)



The DMRC Orthodontic Band Cement (**Table 2**) should be compared to the predicate material in terms of:

- Flexural Strength – ISO 4049, >80 Mpa
- Depth of Cure – ISO 4049, >1.5 mm
- Sensitivity to Ambient Light – ISO 4049, Homogeneous at 60 sec

Additional property comparisons are also listed, namely for Diametral Strength (ADA Specification No. 27) and Vicker's Hardness that show equivalence to the predicate materials.

For Shear Bond Strength (SBS), Reynolds<sup>a</sup> and others<sup>b</sup> indicated that the minimum SBS for the orthodontic treatment is from 6 to 8 MPa. The DMRC Orthodontic Band Cement (Table 2) is over this value range together with the predicate material.

*References:*

Reynolds, I. R. "A review of direct orthodontic bonding", *British Journal of Orthodontics*, 1975: 2, 171-178.

Oral Sokucu et al, *Shear Bond Strength of Orthodontic Brackets Cured with Different Light Sources under Thermocycling*", *Eur J Dent*. 2010; 4(3): 257-262

**H. Biocompatibility Testing**

DMRC Dual Cure Orthodontic Band Cement: b(4)

b(4)

**I. Sterilization and Shelf Life**

Device is a single use device. Sterilization is not required.  
Shelf life is 2 years from the manufactured date.

If any additional information or clarification is required, please contact the undersigned,

Sincerely yours,



Dong Hua

Regulatory Affairs Director and QA Manager  
Phone: 800/827-7940 or 925/973-0710 ext 212  
Fax: 925/973-0764  
Email: [dhua@daneng.com](mailto:dhua@daneng.com)

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>	<b>PAYMENT IDENTIFICATION NUMBER:</b> b(4) Write the Payment Identification number on your check.
---	---

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <http://www.fda.gov/oc/mdufma/coversheet.html>

<b>1. COMPANY NAME AND ADDRESS</b> (include name, street address, city state, country, and post office code)  DANVILLE MATERIALS, LLC 3420 FOSTORIA WAY, SUITE A-200 SAN RAMON CA 94583 US <b>1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)</b> *****6224	<b>2. CONTACT NAME</b> Lindsay Tilton <b>2.1 E-MAIL ADDRESS</b> dhua@daneng.com <b>2.2 TELEPHONE NUMBER (include Area code)</b> 925-9730710 <b>2.3 FACSIMILE (FAX) NUMBER (Include Area code)</b>
---	---

**3. TYPE OF PREMARKET APPLICATION** (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm>)

<u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	<b>3.1 Select a center</b> <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER <b>3.2 Select one of the types below</b> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
--	--

**4. ARE YOU A SMALL BUSINESS?** (See the instructions for more information on determining this status)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA      NO, I am not a small business

**4.1 If Yes, please enter your Small Business Decision Number:** b(4)

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <http://www.fda.gov/cdrh/mdufma> for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

This application is the first PMA submitted by a qualified small business, including any affiliates

The sole purpose of the application is to support conditions of use for a pediatric population

This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

YES  NO

#### PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002  
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

b(4)

30-Sep-2014

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

# Please wait...

If this message is not eventually replaced by the proper contents of the document, your PDF viewer may not be able to display this type of document.

You can upgrade to the latest version of Adobe Reader for Windows®, Mac, or Linux® by visiting [http://www.adobe.com/go/reader\\_download](http://www.adobe.com/go/reader_download).

For more assistance with Adobe Reader visit <http://www.adobe.com/go/acrreader>.

Windows is either a registered trademark or a trademark of Microsoft Corporation in the United States and/or other countries. Mac is a trademark of Apple Inc., registered in the United States and other countries. Linux is the registered trademark of Linus Torvalds in the U.S. and other countries.



[www.danvillematerials.com](http://www.danvillematerials.com)  
3420 Fostoria Way Suite A-200  
San Ramon,, CA 94583 USA

---

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HZ-401)  
1390 Piccard Drive  
Rockville, Maryland 20850

Date: 09/05/2014

Subject: Company Cover Letter for a **Traditional 510(K)** Submission

Attention: Document Mail Room Staff

In accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in conformance with 21 CFR 807, this premarket notification is being submitted at least 90 days prior to the date when Danville Manufacturing DBA Danville Engineering proposes to introduce into interstate commerce for commercial distribution a *Light Cure Orthodontic Adhesive* to be known as DMRC Light Cure Orthodontic Adhesive.

The following information is being also covered on the CDRH Premarket Review Submission Cover Sheet:

- A. Establishment registration number:  
Registration Number is **2954330**  
Danville Materials LLC  
3420 Fostoria Way Suite A-200  
San Roman, CA 94583  
USA
- B. The common name of the device:  
Dental adhesive, bracket and tooth conditioner, Resin
- C. Trade Name (proprietary name):  
**DMRC Dual Cure Orthodontic Band Cement** – Model Number: 60024
- D. The classification name of the device:  
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
- E. The reason for the 510(K):  
A new device



**Danville**  
ENGINEERING & MATERIALS

[www.danvillematerials.com](http://www.danvillematerials.com)

3420 Fostoria Way Suite A-200  
San Ramon,, CA 94583 USA

- 
- F. The legally marketed device (predicate) to the claim Substantial Equivalence (SE)  
K123348 CLEAR ALIGNER ADHESIVE By RELIANCE ORTHODONTIC PRODUCTS, INC
- G. Additional facility - DMRC facility also manufactures the finished device,

Registration Number is **3010664129**  
Danville Materials Research Center  
4020 E Leaverton CT  
Anaheim, CA 92807  
USA

If any additional information or clarification is required, please contact the undersigned at (925)  
973-0710. Ext. 212

Sincerely yours,

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212  
Mobile Phone: 510-364-7842  
Fax: 925/973-0764  
Email: [dhua@daneng.com](mailto:dhua@daneng.com)

**004\_Table of Contents (DMRC Dural Cure Orthodontic Band Cement)**

<b>Item #</b>	<b>Item Description</b>	<b>Total Page#</b>
001_	Medical Device User Fee Cover Sheet Form 3601	1
002_	CDRH Premarket Review Submission Cover Sheet	5
003_	510(K) Company Cover Letter	2
004_	Table of Contents (DMRC Dural Cure Orthodontic Band Cement)	1
005_	Indications for Use Statement	1
006_	510(K) Summary	4
	A. A Device Name/Description	
	B. Establishment Registration Number	
	C. Recognized Standards	
	D. Labeling	
	E. Predicate Devices	
	F. Chemical Identity	
	G. Physical and Mechanical Properties	
	H. Biocompatibility Testing	
I. Sterilization and Shelf Life		
007_	Premarket Notification Truthful and Accuracy Statement 21 CFR 807.87(k)	1
008_	Proposed Labeling and Instruction For Use	2
009_	Premarket Notification Statement 21 CFR 807.93	1
010_	Biocompatibility _14-02873-G1	20
011_	Danville Test Method A_Vicker's Hardness	4
012_	Danville Test Method B_Ultradent Bracket Shear Bond Strength (SBS)	7
013_	Danville Test Method C_WT/ST for Ortho Products	2
014_	Other (MSDS on raw chemical materials in major ingredients)	49

## Indications for Use

510(k) Number (if known)

Device Name

DMRC Dual Cure Orthodontic Band Cement

Indications for Use (Describe)

This device is a two paste dual-cure adhesive intended for use as an orthodontic band cement for cementation of orthodontic bands

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:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"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."*

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HZ-401)  
1390 Piccard Drive  
Rockville, Maryland 20850

September 5, 2014

Re: 510(k) Notification

Attention: Document Control Clerk

In accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in conformance with 21 CFR 807, this premarket notification is being submitted at least 90 days prior to the date when Danville Manufacturing dba Danville Engineering proposes to introduce into interstate commerce for commercial distribution a Dual Cure Orthodontic Band Cement to be known as Dual Cure Orthodontic Band Cement.

The following information is being submitted in conformance with 21 CFR 807.87:

**A. Device Name/Description:**

*Trade/Proprietary Name: DMRC Dual Cure Orthodontic Band Cement:*

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.

Device Description: This device is a two paste dual-cure adhesive intended for use as an *orthodontic band cement*.

**B. Establishment Registration Number: 2954330**

**C. Recognized Standards:**

ISO 4049 is the recognized consensus standard applicable to Polymer based filling and restorative materials. ADA Specification 27 is another recognized standard for Polymer based restorative materials. Since the composition of the DMRC Dual Cure Orthodontic Band Cement listed in Section A is the same as polymer based filling and restorative materials, ISO 4049 tests were performed. The specific tests performed were Flexural Strength in both Light Cure and Self Cure modes, Sensitivity to Ambient Light, Depth of Cure. Diametral Strength measurements were also carried out according to ADA Specification No. 27.

For adhesive tests such as Shear Bond Strength on Enamel, a proprietary test method was used similar to ISO 11405 which is the recognized consensus standard applicable to Dental Adhesives, see 012\_Danville Test Method B\_Ultradent Bracket Shear Bond Strength (SBS). Proprietary test methods were used for Set Time measurement, see 013\_Danville Test Method C\_WT/ST for Ortho Products and determination of Vicker's hardness, see 011\_Danville Test Method A\_Vicker's Hardness.

**D. Labeling:**

The Instructions, labeling and packaging for DMRC Dual Cure orthodontic Band Cement are enclosed in 008\_Proposed Labeling and IFU.

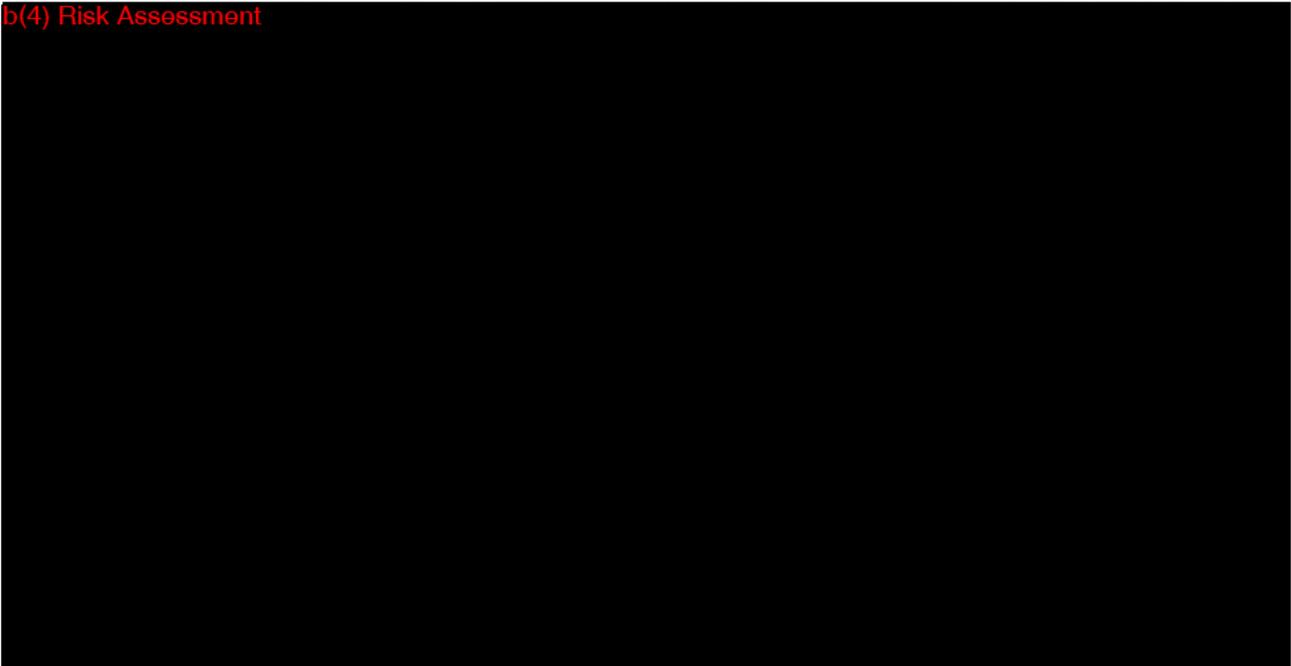
**E. Predicate Devices:**

DMRC Dual Cure Orthodontic Band Cement: Band Lok, marketed by Reliance Orthodontic Corp.

The equivalence of DMRC Dual Cure Orthodontic Band Cement to the predicate device is supported by **Table 2** and the enclosures following:

**Table 2.** Physical Properties of DMRC Dual Cure Orthodontic Band Cement

b(4) Risk Assessment



The following materials for DMRC Dual Cure Orthodontic Band Cement are enclosed in the 004\_Table of Contents\_DMRC Dual Cure Orthodontic Band Cement:

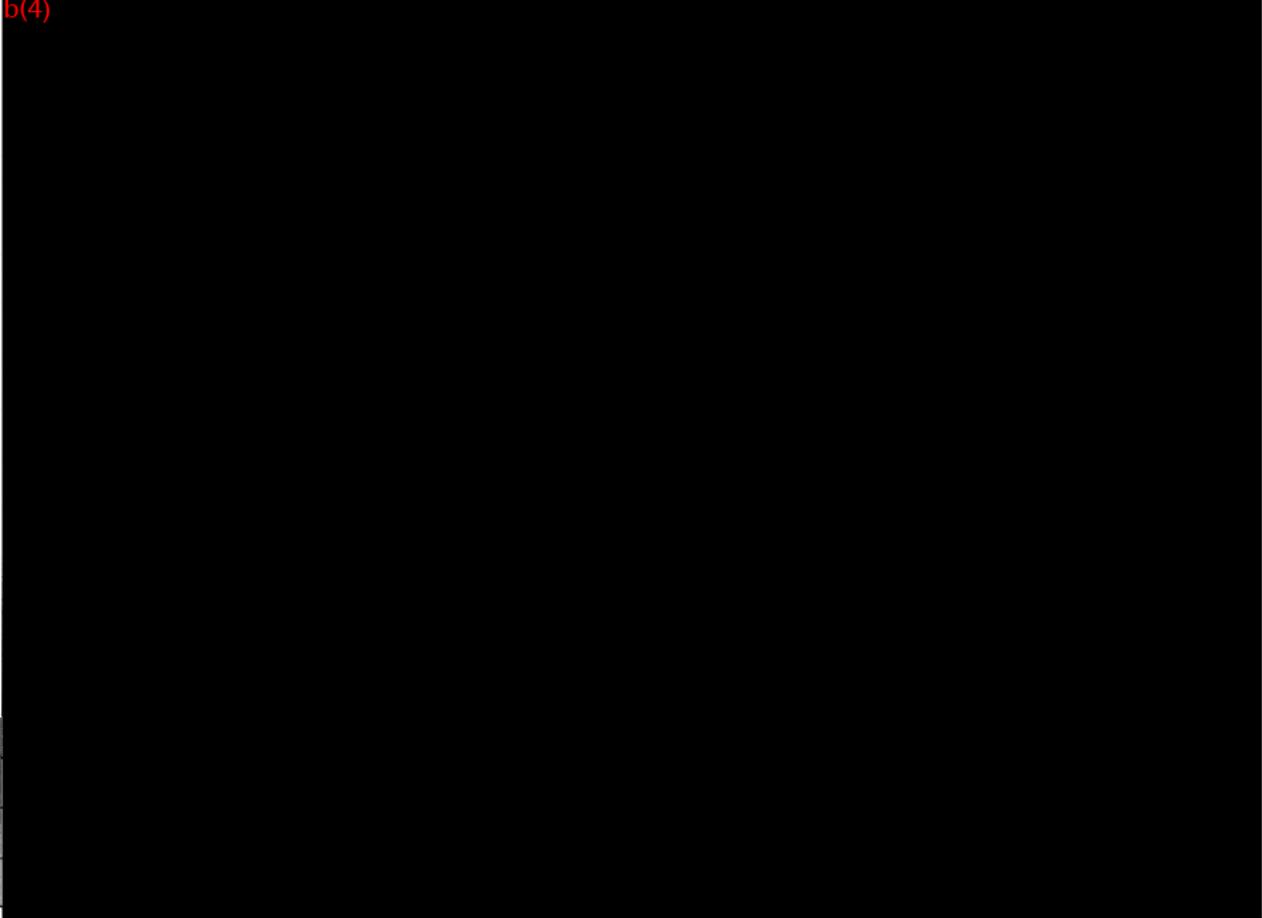
1. Instruction Manual: 008\_Proposed Labeling and IFU
2. Product Labeling: 008\_Proposed Labeling and IFU
3. Premarket Notification Statement 21 CFR 807.93: 009\_Premarket Notification Statement 21 CFR 807.93
4. Premarket Notification Truthful and Accurate Statement 21 CFR 807.87(k): 007\_Truthful and Accurate Statement
5. Indications for Use Form: 005\_Indications for Use Statement
6. Danville Test Method A: 011\_Danville Test Method A\_Vickier's Hardness
7. Danville Test Method B: 012\_Danville Test Method B\_Ultradent Bracket Shear Bond Strength (SBS)
8. Danville Test Method C: 013\_Danville Test Method C\_WT/ST for Ortho Products

**F. Chemical Identity:**

The name, function and CAS number of each component of this product is identified in **Table 4.**

**Table 4.** Material Component Description

b(4)

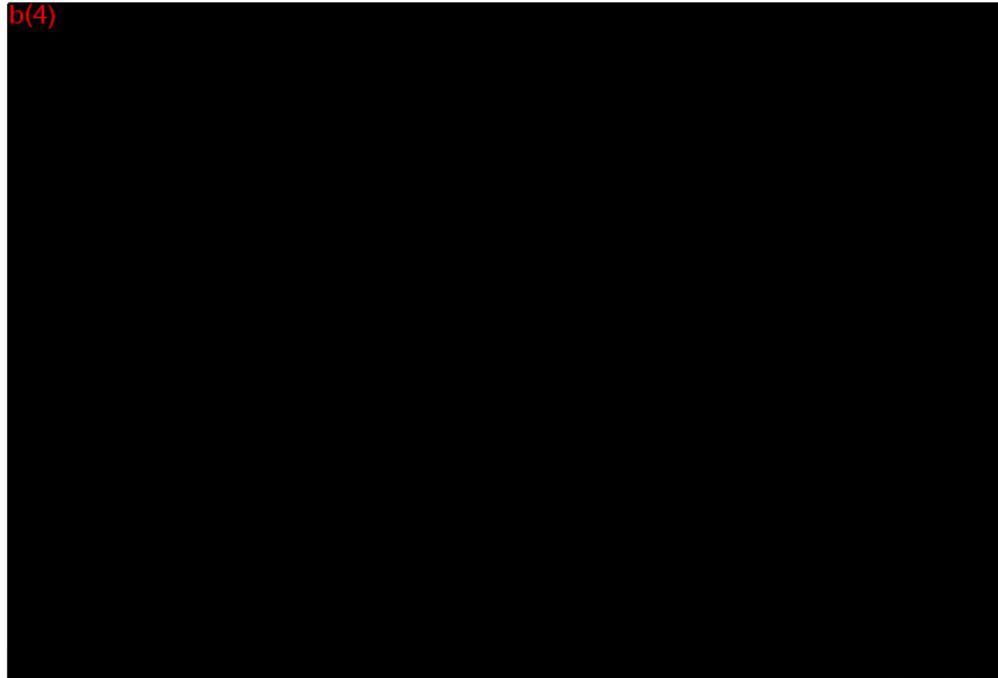


Chemical raw materials are purchased from well established vendors, The MSDS sheets for the main chemical components and a diagram of the chemical structure and the molecular formula of the finished material are enclosed in 014\_Other (MSDS on raw chemical materials in major ingredients).

The complete formulation for this product, identifying the individual chemical components by percentage to a sum of 100% are attached in **Table 5**.

**Table 5.** Composition of Orthodontic Adhesives and Band Cement

b(4)

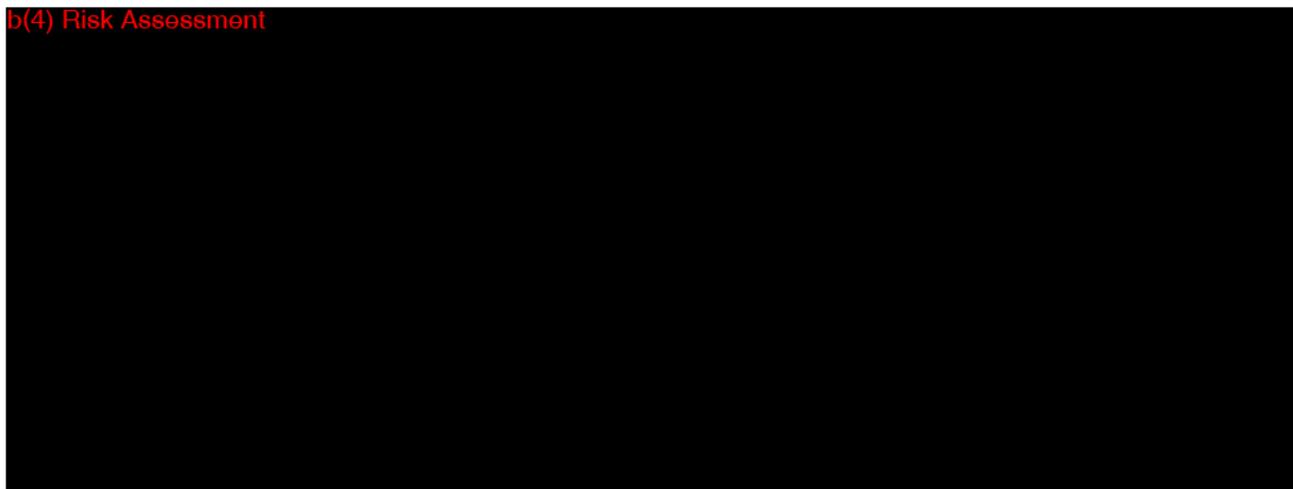


### **G. Physical and Mechanical Properties**

The Physical Properties of the product is shown in the Tables 2.

**Table 2.** Physical Properties of DMRC Dual Cure Orthodontic Band Cement

b(4) Risk Assessment



The DMRC Orthodontic Band Cement (**Table 2**) should be compared to the predicate material in terms of:

- Flexural Strength – ISO 4049, >80 Mpa
- Depth of Cure – ISO 4049, >1.5 mm
- Sensitivity to Ambient Light – ISO 4049, Homogeneous at 60 sec

Additional property comparisons are also listed, namely for Diametral Strength (ADA Specification No. 27) and Vicker's Hardness that show equivalence to the predicate materials.

For Shear Bond Strength (SBS), Reynolds<sup>a</sup> and others<sup>b</sup> indicated that the minimum SBS for the orthodontic treatment is from 6 to 8 MPa. The DMRC Orthodontic Band Cement (**Table 2**) is over this value range together with the predicate material.

*References:*

Reynolds, I. R. "A review of direct orthodontic bonding", *British Journal of Orthodontics*, 1975: 2, 171-178.

Oral Sokucu et al, *Shear Bond Strength of Orthodontic Brackets Cured with Different Light Sources under Thermocycling*", *Eur J Dent*. 2010; 4(3): 257-262

**H. Biocompatibility Testing**

DMRC Dual Cure Orthodontic Band Cement: b(4)

b(4)

**I. Sterilization and Shelf Life**

Device is a single use device. Sterilization is not required.  
Shelf life is 2 years from the manufactured date.

If any additional information or clarification is required, please contact the undersigned,

Sincerely yours,



Dong Hua

Regulatory Affairs Director and QA Manager  
Phone: 800/827-7940 or 925/973-0710 ext 212  
Fax: 925/973-0764  
Email: [dhua@daneng.com](mailto:dhua@daneng.com)



---

## Premarket Notification Truthful And Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as *President* of *Danville Materials LLC*, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Craig Bruns

(Typed Name)

9/5/2014

(Date)

008\_Proposed Labeling and IFU \_DMRC Dual Cure Orthodontic Band Cement

**DMRC Dual Cure**  
ORTHODONTIC BAND CEMENT  
REF 60024 5  
GM  
 Danville   
FAX 925/973-0764 800/827-7940  
MADE IN USA  
LOT XXXXX  XXXX/XX



## **Instructions for Use**

### **Dual Cure Orthodontic Band Cement**

#### **Application**

**Step 1.** Lightly roughen the inside of the band with a fine diamond bur or microetcher.

**Step 2.** Prophyl, rinse, dry and isolate tooth to be banded. Acid etching of the enamel is not required for cementing bands, however, it will increase strength required for high stress appliances.

**Step 3.** On a mixing pad place equal parts of Dual Cure Orthodontic Band Cement, Pastes A and B (A 1 inch strip of each part will provide enough cement for 4 bands). If paste is not going to be mixed immediately, shield from light.

**Step 4.** Mix Pastes A and B thoroughly for 10 seconds and place in band. Seat band and clean off excess flash.

**Step 5.** At this point you have three curing options:

a) With a dental curing light, cure the cement from the occlusal surface for 10 seconds. Cement can be exposed to saliva at this point. Final cure will occur in 5 minutes.

b) With a dental curing light, cure the cement from the occlusal surface for 40 seconds. Cement is now completely cured and can be exposed to headgear forces immediately.

c) Allow the cement to chemically cure on its own; complete polymerization will occur in 10 minutes.

#### **Precautions and Warnings**

Uncured resin material can cause irritation. Wash hands after handling material. The bonded materials are formulated to be used at room temperature. Shelf life is two years when handled properly. Kits can be refrigerated to extend shelf life.

Do not store materials in the proximity to eugenol-containing products.

Do not expose materials to elevated temperatures or intense light.

Etchant contains 38% phosphoric acid which is harmful to skin and eyes. In case of eye contact, flush with water and seek immediate medical assistance.

Store at 72°F (22°C).



---

# Premarket Notification 510(k) Statement

(As Required By 21 CFR 807.93)

I certify that, in my capacity as *President of Danville Materials LLC*, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(Signature of Certifier)

Craig Bruns

(Typed Name)

(Date)

9/5/2014





































































































































































U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 10/28/2014

Subject: Response to K142881 – Refuse To Accept (RTA) Checklist

**001\_Cover Letter K142881 RTA Response**

Dear FDA Officer,

Please review the following information for our response to the RTA notification,

- A. FDA Notification:  
October 21, 2014 **Acceptance Review Notification - Refuse To Accept (RTA) K142881** is on Hold Pending Your Response (Attached RTA Checklist, 10 pages)
- B. Submission Number: **K142881**  
Applicant: **Danville Materials LLC**  
Submitter: **Dong Hua**  
Device: **DMRC Dual Cure Orthodontic Band Cement**
- C. Table of Contents (Response to 510(K) RTA hold letter in an individual PDF file)

Item #	Item Description	Total Page#
001_Cover Letter	Cover Letter K142881 RTA Response	3
002_RTAChecklist	K142881.RTAChecklist.RTA1	10
003_Item 4a	510(K) Summary Checklist	5
004_Item 8	Standards Data Report for 510(K)s FORM 3654	5
005_Item 9	Statement on prior submissions for the subject device	1
006_Item 10	Device Specific Requirements	1
007_Item 11	Descriptive Information	1
008_Item 12	Device Engineering drawing/figure information	1
009_Item 14	Predicate device information	2
010_Item 15	Comparison of the predicate and subject device	2
011_Item 16	Analysis on the subject device and predicate	3
012_Item 17	Proposed Labeling	2
013_Item 20	Statement on Device Specific Guidance	1
014_Item 28	Statement On the summary of methods	2
015_Item 29 Item 30	Information regarding the patient contact status	1



[www.danvillematerials.com](http://www.danvillematerials.com)  
3420 Fostoria Way Suite A-200  
San Ramon, CA 94583 USA

G. eCopy Statement:  
**The eCopy is an exact duplicate of the paper copy**

If any additional information or clarification is required, please contact the undersigned at (925) 973-0710. Ext. 212

Sincerely yours,

A handwritten signature in blue ink, consisting of several loops and a long horizontal stroke extending to the right.

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212  
Mobile Phone: 510-364-7842  
Fax: 925/973-0764  
Email: [dhua@daneng.com](mailto:dhua@daneng.com)

U.S. Food and Drug Administration  
 Center for Devices and Radiological Health  
 Document Control Center – WO66-G609  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20993-0002

Date: 10/28/2014

Subject: Response to K142881 – Refuse To Accept (RTA) Checklist

**001\_Cover Letter K142881 RTA Response**

Dear FDA Officer,

Please review the following information for our response to the RTA notification,

- A. FDA Notification:  
 October 21, 2014 **Acceptance Review Notification - Refuse To Accept (RTA) K142881** is on Hold Pending Your Response (Attached RTA Checklist, 10 pages)
- B. Submission Number: **K142881**  
 Applicant: **Danville Materials LLC**  
 Submitter: **Dong Hua**  
 Device: **DMRC Dual Cure Orthodontic Band Cement**
- C. Table of Contents (Response to 510(K) RTA hold letter in an individual PDF file)

Item #	Item Description	Total Page#
001_Cover Letter	Cover Letter K142881 RTA Response	3
002_RTAChecklist	K142881.RTAChecklist.RTA1	10
003_Item 4a	510(K) Summary Checklist	5
004_Item 8	Standards Data Report for 510(K)s FORM 3654	5
005_Item 9	Statement on prior submissions for the subject device	1
006_Item 10	Device Specific Requirements	1
007_Item 11	Descriptive Information	1
008_Item 12	Device Engineering drawing/figure information	1
009_Item 14	Predicate device information	2
010_Item 15	Comparison of the predicate and subject device	2
011_Item 16	Analysis on the subject device and predicate	3
012_Item 17	Proposed Labeling	2
013_Item 20	Statement on Device Specific Guidance	1
014_Item 28	Statement On the summary of methods	2
015_Item 29 Item 30	Information regarding the patient contact status	1



[www.danvillematerials.com](http://www.danvillematerials.com)

3420 Fostoria Way Suite A-200  
San Ramon, CA 94583 USA

G. eCopy Statement:

**The eCopy is an exact duplicate of the paper copy**

If any additional information or clarification is required, please contact the undersigned at (925) 973-0710. Ext. 212

Sincerely yours,

A handwritten signature in blue ink, appearing to read "Dong Hua", with a long horizontal flourish extending to the right.

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212  
Mobile Phone: 510-364-7842  
Fax: 925/973-0764  
Email: [dhua@daneng.com](mailto:dhua@daneng.com)



Contains Nonbinding Recommendations

Print Form

# Acceptance Checklist for Traditional 510(k)s

**(Should be completed within 15 days of DCC receipt)**

The following information is not intended to serve as a comprehensive review.

510(k) #: K142881

Date Received by DCC: Oct 10, 2014

Lead Reviewer: Phillip Woods, DDS, MPH

Branch: DEDB

Division: DAGRID

Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

<b>Preliminary Questions</b>		
Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
<p><b>1) Is the product a device (per section 201(h) of the FD&amp;C Act) or a combination product (per <a href="#">21 CFR 3.2(e)</a>) with a device constituent part subject to review in a 510(k)?</b></p> <p>If it appears not to be a device (per section 201(h) of the FD&amp;C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If the product does not appear to be a device or such a combination product, mark "No."</p>	X	
Comments?		
<p><b>2. Is the application with the appropriate Center?</b></p> <p>If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If application should not be reviewed by your Center mark "No."</p>	X	
Comments?		
<p><b>3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:</b></p> <p>a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?</p> <p>b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ?</p> <p>If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.</p>		
Comments?		
<p><b>4) Is this device type eligible for a 510(k) submission?</b></p> <p>If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."</p>	X	
Comments?		

<p><b>5) Is there a pending PMA for the same device with the same indications for use?</b></p> <p>If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.</p>		X
Comments?		
<p><b>6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?</b></p> <p>If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at <a href="http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm">http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm</a></p>		X
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.

If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.

If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.

If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

## **Organizational Elements**

*Failure to include these items alone generally should not result in an RTA designation.*

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

## Elements of a Complete Submission (RTA Items)

**(21 CFR 807.87 unless otherwise indicated)**

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

- Any "No" answer will result in a "Refuse to Accept" decision.  
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

**Yes**

**No**

**N/A**

**Comment**

### **A. Administrative**

1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	✗			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet ( <a href="#">Form 3514</a> ) or 510(k) cover letter):	✗			
a) Device trade name or proprietary name	✗			
b) Device common name	✗			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	✗			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also <a href="#">21 CFR 801.109</a> ).	✗			
4) Submission contains 510(k) Summary or 510(k) Statement	✗			✗
a) Summary contains all elements per <a href="#">21 CFR 807.92</a> (See also <a href="#">510(k) Summary Checklist</a> )		✗		
b) Statement contains all elements per <a href="#">21 CFR 807.93</a>			✗	
Comments?	Summary does not contain all elements per 21 CFR 807.92 (See also 510(k) Summary Checklist).			
5) Submission contains Truthful and Accuracy Statement per <a href="#">21 CFR 807.87(k)</a> See recommended <a href="#">format</a> .	✗			
6) Submission contains Class III Summary and Certification. See recommended <a href="#">content</a> .		✗		
7) Submission contains clinical data			✗	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s ( <a href="#">Form 3654</a> ) or includes detailed information about how and the extent to which the standard has been followed.		✗		✗
Comments?	Submission references use of a national or international standard as part of demonstration of substantial equivalence, but submission does not contain Standards Data Report for 510(k)s (Form 3654) or include detailed information about how and the extent to which the standard has been followed.			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.		✗		✗
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance " <a href="#">Medical Devices: The Pre-Submission Program and Meetings with FDA Staff</a> ." Once finalized, this guidance will represent the Agency's current thinking on this topic.			✗	

## Elements of a Complete Submission (RTA Items)

**(21 CFR 807.87 unless otherwise indicated)**

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Comment</b>
---	------------	-----------	------------	----------------

**Comments?** The submission does not identify prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.

### **B. Device Description**

10)				×
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.		×		
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.				

**Comments?** If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission does not include device description information to establish that the submitter has followed the device specific requirement.

11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				×
a) A description of the principle of operation and mechanism of action for achieving the intended effect.		×		
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.		×		
c) A list and description of each device for which clearance is requested.	×			

**Comments?** Descriptive information is not present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:  
 a) A description of the principle of operation and mechanism of action for achieving the intended effect.  
 b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.

12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.		×		×
<b>Comments?</b> Submission does not contain representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.				
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system			×	

## Elements of a Complete Submission (RTA Items)

**(21 CFR 807.87 unless otherwise indicated)**

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

- Any "No" answer will result in a "Refuse to Accept" decision.  
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

**Yes**

**No**

**N/A**

**Comment**

### **C. Substantial Equivalence Discussion**

14) Submitter has identified a predicate device.	×			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding <a href="#">documenting preamendment status</a> is available online.</i>	×			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.		×		
15) Submission includes a comparison of the following for the predicate(s) and subject device				×
a) Indications for Use		×		
b) Technology, including features, materials, and principles of operation		×		
Comments? Submission does not include a comparison of the following for the predicate(s) and subject device a) Indications for Use b) Technology, including features, materials, and principles of operation				
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate ), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and <a href="#">21 CFR 807.87(f)</a> )		×		×
Comments? Submission does not include an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are not accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate ), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)).				
<b>D. Proposed Labeling (see also 21 CFR part 801)</b>				
If <i>in vitro</i> diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.		×		×
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).		×		

## Elements of a Complete Submission (RTA Items)

**(21 CFR 807.87 unless otherwise indicated)**

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

	Yes	No	N/A	Comment
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.				
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see <a href="#">21 CFR 801.5</a> ) OR submission states that device qualifies for exemption per <a href="#">21 CFR 801 Subpart D</a>		×		
<b>Comments?</b> Submission does not include proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use. a) Indications for use are not stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided). b) Submission does not include directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D.				
18) If indicated for prescription use, labeling includes the prescription use statement (see <a href="#">21 CFR 801.109(b)(1)</a> ) or "Rx only" symbol [See also <a href="#">Alternative to Certain Prescription Device Labeling Requirements</a> ]	×			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor ( <a href="#">21 CFR 801.1</a> ).	×			
b) Labeling includes device common or usual name. ( <a href="#">21 CFR 801.61</a> )	×			
20)				×
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			×	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.		×		
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			×	
<b>Comments?</b> If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.				
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per <a href="#">21 CFR 809.10</a> .			×	

## Elements of a Complete Submission (RTA Items)

**(21 CFR 807.87 unless otherwise indicated)**

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Comment</b>
---	------------	-----------	------------	----------------

### E. Sterilization

If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.			×	
--	--	--	---	--

### F. Shelf Life

26) Proposed shelf life/expiration date stated	×			
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.			×	
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.		×		×

**Comments?** Submission does not include summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.

### G. Biocompatibility

If IVD device, select "N/A" and the below criteria will be omitted from checklist.				×
--	--	--	--	---

Submission states that there: (one of the below must be checked)				
are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
×	Information regarding the patient contact status of the device is not provided.			

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

**Comments?** Information regarding the patient contact status of the device is not provided.

29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	×			
30) Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration, etc.)		×		×

**Comments?** Submission does not identify contact classification (e.g., surface-contacting, less than 24 hour duration, etc.).

31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	×			
--	---	--	--	--

### H. Software

## **Elements of a Complete Submission (RTA Items)**

**(21 CFR 807.87 unless otherwise indicated)**

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

- Any "No" answer will result in a "Refuse to Accept" decision.  
- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

**Yes**

**No**

**N/A**

**Comment**

Submission states that the device: (one of the below must be checked)

does contain software/firmware.

does not contain software/firmware.

Information regarding whether the device contains software is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

### **I. EMC and Electrical Safety**

Submission states that the device: (one of the below must be checked)

does require EMC and Electrical Safety evaluation.

does not require EMC and Electrical Safety evaluation.

Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

### **J. Performance Data - General**

If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.

### **K. Performance Characteristics - In Vitro Diagnostic Devices Only**

(Also see [21 CFR 809.10\(b\)\(12\)](#))

Submission states that the device: (one of the below must be checked)

is an in vitro diagnostic device.

is not an in vitro diagnostic device.

**Decision:**     Accept     Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

**Digital Signature Concurrence Table**

Reviewer Sign-Off	Phillip D. Woods -S 2014.10.21 09:08:55 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

\* Branch and Division review of checklist and concurrence with decision required.  
Branch and Division digital signature optional.



U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 10/28/2014

Subject: Response to K142881– Refuse To Accept (RTA) Checklist

### **003\_Item 4a 510(K) Summary Checklist**

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: October 28, 2014

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

- Trade/Proprietary Name: DMRC Dual Cure Orthodontic Band Cement
- 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 Devices to Which Substantial Equivalence (SE) is claimed:**

- K123348 Clear Aligner Adhesive by Reliance Orthodontic Products, Inc.
- N/A Band Lok by Reliance Orthodontic Products, Inc.
- K111696 Opal<sup>®</sup> Band<sup>™</sup> Cement by Opal Orthodontics by Ultradent Products, Inc.

#### **D. Description of the Device:**

- Indication For Use: The DMRC Dual Cure Orthodontic Band Cement is a two paste dual-cure adhesive intended for use as an orthodontic band cement for cementation of orthodontic bands



- Intended Use of the Device: The DMRC Dual Cure Orthodontic Band Cement is polymer based filling and restorative materials, it contains two pastes (Paste A and B) for dual curing process as orthodontic band cement. This product can be used for patients of all ages

**E. A comparison of the Clear Aligner Adhesive By Reliance Orthodontic Products, Inc and the DMRC Dual Cure Orthodontic Band Cement to determine SE:**

- **Table 1**\_Physical and Mechanical Properties: The DMRC Dual Cure Orthodontic Band Cement vs. Clear Aligner Adhesive by Reliance Orthodontic Products, Inc.

Test Method	Std Ref.	Specification	DMRC Dual Cure Orthodontic Band Cement (132-077B)	Notebook Ref	Clear Aligner Adhesive/Band Lok (Reliance) (14606)	Notebook Ref
Sensitivity to Ambient Light (9300 Lux)	ISO 4049	Homogeneous at 60 sec	Pass	132-154B	Pass	132-167C
Depth of Cure, mm (10sec @ 500mw/cm <sup>3</sup> ) (4mm x 12mm mold)	ISO 4049	> 1.5	2.2	132-079B	2.5	132-147B
Flexural Strength (MPa) - Light Cure	ISO 4049	> 80	95.6 (20.5)	132-079D	106.3 (17)	132-167A
Flexural Strength (MPa) - Self Cure	ISO 4049	> 80	111.2 (13.3)	132-079D	109.4 (8)	132-033C
Diametral Tensile Strength (MPa)-Light Cure	ADA Specification No. 27	NA	43.4 (6)	132-145F	58.7 (2)	132-145E
Diametral Tensile Strength (MPa)- Self Cure	ADA Specification No. 27	NA	54.8 (2)	132-145F	48.3 (2)	132-145E
Bottom Vicker's Hardness at 2 mm (40sec @ 1300mW/cm <sup>3</sup> )	Danville Test Method A	NA	86 (8)	132-190B	73 (3)	132-190A
Set Time (min) Self Cure	Danville Test Method C	NA	6:00	132-079C	7:30	132-147A
Shear Bond Strength on enamel (MPa) with E-Bond	ISO 11405 Method	NA	23.6 (7.2)	132-148B	17.6 (7)	132-165A
Shear Bond Strength on enamel (MPa) without E-bond	ISO 11405 Method	NA	13.4 (5.6)	132-148A	18.3 (4.5)	132-181A

The DMRC Dual Cure Orthodontic Band Cement (**Table 1**) should be compared to the predicate material in terms of:

- Flexural Strength – ISO 4049, >80 Mpa
- Depth of Cure – ISO 4049, >1.5 mm
- Sensitivity to Ambient Light – ISO 4049, Homogeneous at 60 sec
- Additional property comparisons are also listed,
  - Vicker’s Hardness
  - ultradent bracket Shear Bond Strength (SBS) on Enamel that show equivalence to

- the predicate material.
- Ultradent Bracket Shear Bond Strength (SBS), which is similar to ISO 11405. This ISO standard is the recognized consensus standard applicable to Dental Adhesives.
  - Chemical Identity: **Table 2\_ Material Component Description**

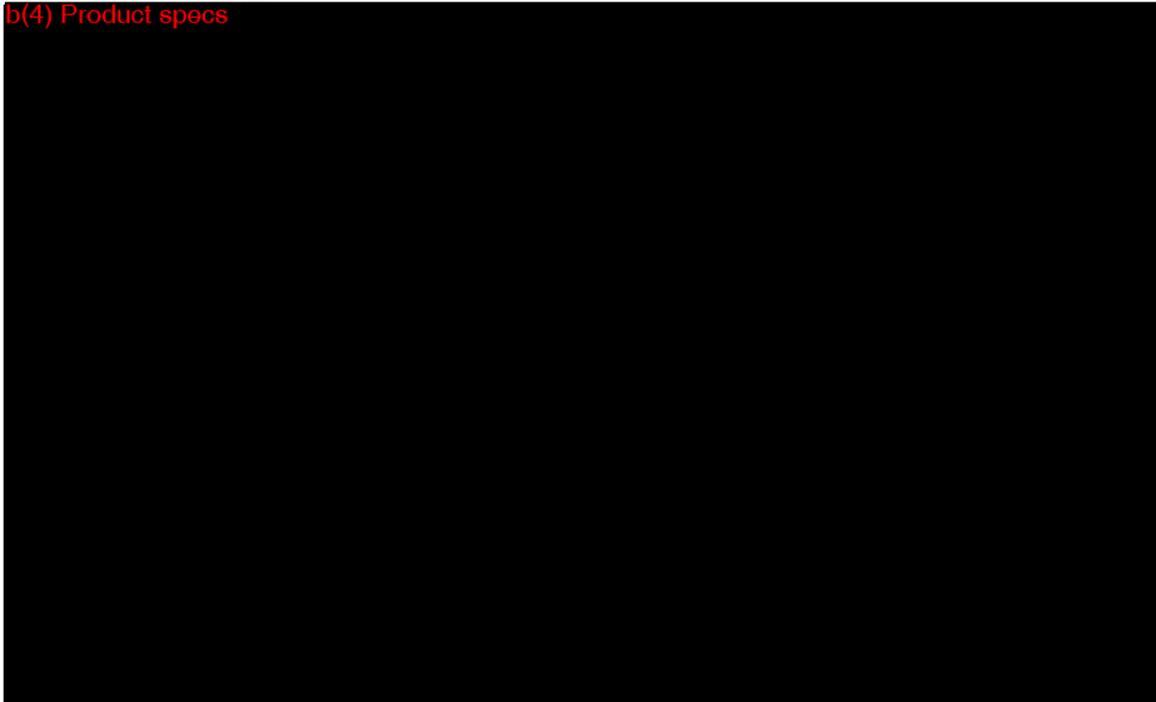
b(4) Product specs



Chemical raw materials are purchased from well established vendors, the MSDS sheets on raw chemical materials in major ingredients is available.

The complete formulation for the product, identifying the individual chemical components by percentage to a sum of 100% is attached in **Table 3\_ Composition of DMRC Dual Cure Orthodontic Band Cement**

b(4) Product specs



➤ Similarities in the Indications for Use:

Product	510(K) Number	Classification Name	Indications For Use
Reliance Orthodontic Product, Inc's Clear Aligner Adhesive	K123348	Bracket Adhesive Resin and Tooth Conditioner	An orthodontic bonding adhesive for brackets and appliances to thermoplastic aligner surfaces
Opal Orthodontics by Ultradent Products, Inc's Opal ®Band™ Cement	K111696	Bracket Adhesive Resin and Tooth Conditioner	Uses chemical, light and glass ionomer polymerization to cement all types of orthodontic bands to the teeth
DMRC Dual Cure Orthodontic Band Cement	New (K142881)	Bracket Adhesive Resin and Tooth Conditioner	A two paste dual-cure adhesive intended for use as an orthodontic band cement for cementation of orthodontic bands

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

DMRC Dual Cure Orthodontic Band Cement is a resin based material containing two paste dual-cure adhesive for cementation of orthodontic bands. The materials used in DMRC Dual Cure Orthodontic Band Cement are the same as used by our predicates, Reliance Orthodontic Product, Inc's Clear Aligner Adhesive (K123348), Opal ®Band™ Cement by Opal Orthodontics (K111696), and/or Band Lok which is the similar dental adhesive products; Band



Lok has no 510(K) number available in the database. These materials have been widely used by numerous manufacturers in the medical/dental industry.

All testing performed on the DMRC Dual Cure Orthodontic Band Cement was derived from the risk assessment which evaluated the effects of the feature changes. The efficacy or suitability to the intended purpose of DMRC Dual Cure Orthodontic Band Cement 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 DMRC Dual Cure Orthodontic Band Cement performs as well or better than the predicate devices currently on the market.

Discussion of Clinical Tests performed: N/A

**F. Summary of Risk/Benefit Review:**

Considering the safe history of our predicates, Reliance Orthodontic Product, Inc's Clear Aligner Adhesive (K123348), Opal <sup>®</sup>Band <sup>™</sup> Cement by Opal Orthodontics (K111696), and other dental adhesive products such as Band Lok, DMRC Dual Cure Orthodontic Band Cement is considered a safe medical device. 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 subject device, DMRC Dual Cure Orthodontic Band Cement 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 Dual Cure Orthodontic Band Cement is compatible with a high level of protection of health and safety and may be released to the market.

If any additional information or clarification is required, please contact the undersigned at (925) 973-0710. Ext. 212

Sincerely yours,



Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200

San Ramon, CA 94583

Work Phone: 800/827-7940 Ext.212

Mobile Phone: 510-364-7842

Fax: 925/973-0764

Email: [dhua@daneng.com](mailto:dhua@daneng.com)

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 4049:2009 DENTISTRY - POLYMER BASED RESTORATIVE MATERIALS

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #4-181

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: Guidance for Industry and FDA Staff - Dental Composite Resin Devices - Premarket Notification [510(k)]

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 4049:2009 DENTISTRY - POLYMER BASED RESTORATIVE MATERIALS

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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 1 hour 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:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov)

*"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 control number."*

Department of Health and Human Services  
 Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
 (To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11405:2003 Dental Materials - Testing of adhesion to tooth structure

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup> ? .....    

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup> ? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
 If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 11405:2003 Dental Materials - Testing of adhesion to tooth structure

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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 1 hour 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:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

*"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 control number."*

## SECTION I

## UTILIZATION OF STANDARDS

**Note:** Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 4049	ISO	Dentistry - Polymer-based restorative materials	2009	01/01/2009
2	ISO 11405	ISO	Dental materials - Testing of adhesion to tooth structure	2003	01/01/2003
3					
4					
5					
6					
7					

**Please include any additional standards to be cited on a separate page.**

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

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

The burden time for this collection of information is estimated to average 0.5 hour 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:

Department of Health and Human Services  
 Food and Drug Administration  
 Office of Chief Information Officer  
 Paperwork Reduction Act (PRA) Staff  
 1350 Piccard Drive, Room 400  
 Rockville, MD 20850

*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 control number.*



---

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 10/28/2014

Subject: Response to K142881– Refuse To Accept (RTA) Checklist

**005\_Item 9 Statement on prior submissions for the subject device**

I certify that, in my capacity as Regulatory Affair Director and QA Manager, that there was no prior submission for the subject device.

A handwritten signature in blue ink, appearing to be 'Dong Hua', written over a horizontal line.

(Signature)

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212  
Mobile Phone: 510-364-7842  
Fax: 925/973-0764

Email: [dhua@daneng.com](mailto:dhua@daneng.com)

---

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 10/28/2014

Subject: Response to K142881– Refuse To Accept (RTA) Checklist

**006\_Item 10 Device Specific Requirements**

- a) There are no requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device



(Signature)

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212  
Mobile Phone: 510-364-7842  
Fax: 925/973-0764

Email: [dhua@daneng.com](mailto:dhua@daneng.com)

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 10/28/2014

Subject: Response to K142881– Refuse To Accept (RTA) Checklist

**007\_Item 11 Descriptive information**

**a) A description of the principle of operation and mechanism of action for achieving the intended effect**

- A description of the device: The DMRC Dual Cure Orthodontic Band Cement is polymer based filling and restorative materials, it contains two pastes (Paste A and B) for dual curing as orthodontic band cement. This product can be used for patients of all ages

**b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient**

- No surgical technique for implants, no anatomical location of use other than the tooth surfaces, no interacts with other devices or user interface
- A brief procedures on how the device interacts with the patient,
  - Lightly roughen the inside of the band
  - Prophylaxis, rinse, dry and isolate tooth to be banded
  - Place equal parts of Dual Cure Orthodontic Band Cement, Pastes A and B on a mixing pad
  - Mix Pastes A and B thoroughly for 10 seconds and place in band. Seat band and clean off excess flash
  - Cement curing process for a complete polymerization



(Signature)

Dong Hua  
Regulatory Affair Director and QA Manager  
3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212 Fax: 925/973-0764  
Email: [dhua@daneng.com](mailto:dhua@daneng.com)



U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 10/28/2014

Subject: Response to K142881– Refuse To Accept (RTA) Checklist

**008\_Item 12 Device Engineering drawing/figure information**

***RTA –12). Submission does not contain representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.***



(Signature)

Dong Hua

Regulatory Affair Director and QA Manager  
3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212  
Mobile Phone: 510-364-7842  
Fax: 925/973-0764  
Email: [dhua@daneng.com](mailto:dhua@daneng.com)



U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 10/28/2014

Subject: Response to K142881– Refuse To Accept (RTA) Checklist

**009\_Item 14 Predicate device information**

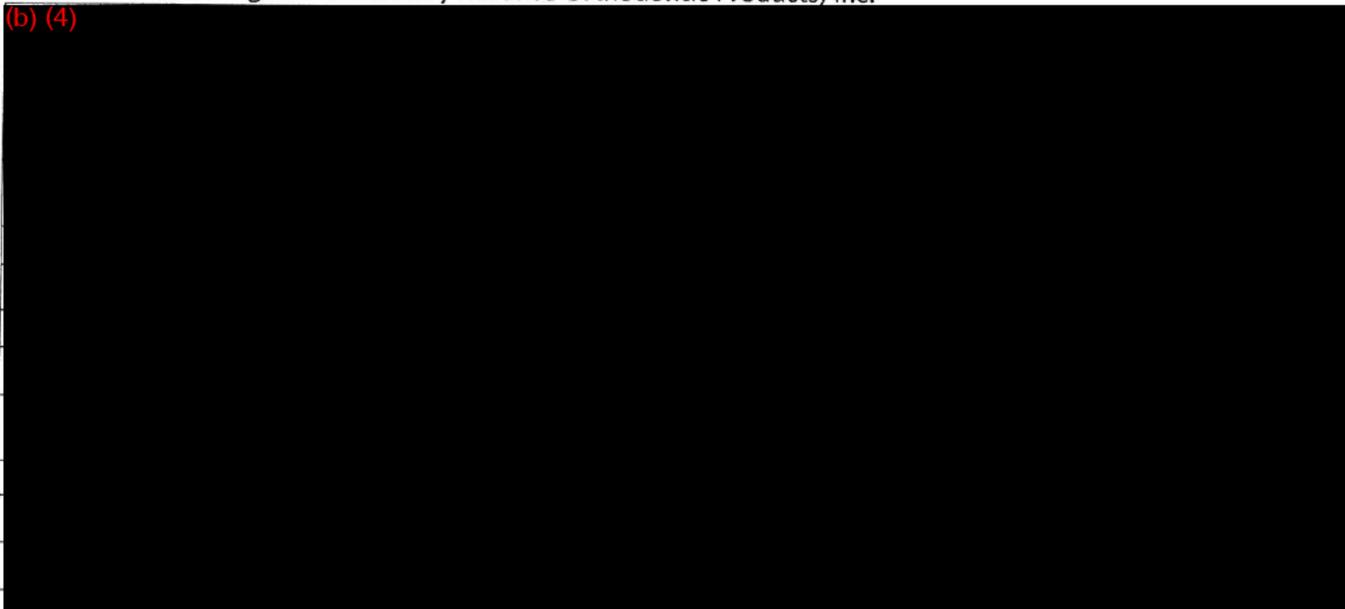
***RTA - 14a. Predicate's 510(K) number, trade name, and model number (if applicable) provided.***

- Legally Marketed Predicate Devices 510(K) number:
  - **K123348: Clear Aligner Adhesive, Band Lok** (510(K) number N/A) By Reliance Orthodontic Products, Inc
  - **K111696: Opal<sup>®</sup> Band<sup>™</sup> Cement** By Opal Orthodontics Ultradent Products, Inc

***RTA – 14b. The identified predicate(s) is consistent throughout the submission (i.e. the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(K) Summary (if applicable) and that used in comparative performance testing.***

- **Table 1.** Physical and Mechanical Properties: The DMRC Dual Cure Orthodontic Band Cement vs. Clear Aligner Adhesive by Reliance Orthodontic Products, Inc.

(b) (4)



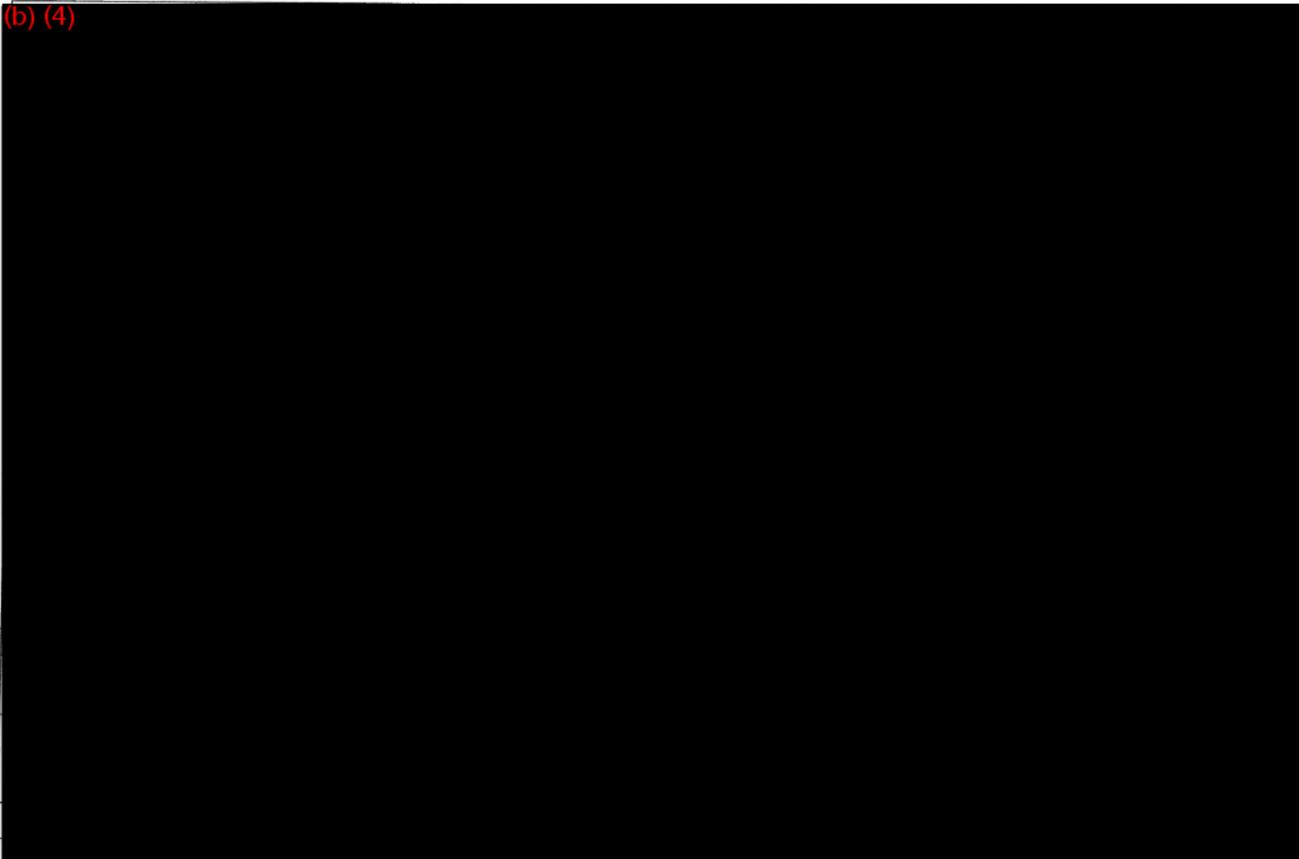
The DMRC Dual Cure Orthodontic Band Cement (**Table 1**) should be compared to the predicate material in terms of:

- Flexural Strength – ISO 4049, >80 Mpa
- Depth of Cure – ISO 4049, >1.5 mm



- Sensitivity to Ambient Light – ISO 4049, Homogeneous at 60 sec
  - Additional property comparisons are also listed,
    - Vicker's Hardness
    - ultradent bracket Shear Bond Strength (SBS) on Enamel that show equivalence.
    - Ultradent Bracket Shear Bond Strength (SBS), which is similar to ISO 11405
- **Table 2.** Chemical Identity: Material Component Description - The name, function and CAS number of each component of the product is identified in,

(b) (4)



(Signature)

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200

San Ramon, CA 94583

Work Phone: 800/827-7940 Ext.212 Fax: 925/973-0764

Email: [dhua@daneng.com](mailto:dhua@daneng.com)

U.S. Food and Drug Administration  
 Center for Devices and Radiological Health  
 Document Control Center – WO66-G609  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20993-0002

Date: 10/28/2014

Subject: Response to K142881– Refuse To Accept (RTA) Checklist

### 010\_Item 15 Comparison of the Predicate and Subject device

**RTA - 15a. Submission includes a comparison of the following for the predicate(s) and subject device, Indications for Use.**

➤ Similarities in the Indications for Use:

Product	510(K) Number	Classification Name	Indications For Use
Reliance Orthodontic Product, Inc's Clear Aligner Adhesive	K123348	Bracket Adhesive Resin and Tooth Conditioner	An orthodontic bonding adhesive for brackets and appliances to thermoplastic aligner surfaces
Opal Orthodontics by Ultradent Products, Inc's Opal ®Band™ Cement	K111696	Bracket Adhesive Resin and Tooth Conditioner	Uses chemical, light and glass ionomer polymerization to cement all types of orthodontic bands to the teeth
DMRC Dual Cure Orthodontic Band Cement	New (K142881)	Bracket Adhesive Resin and Tooth Conditioner	A two paste dual-cure adhesive intended for use as an orthodontic band cement for cementation of orthodontic bands

**RTA – 15b. Submission includes a comparison of the following for the predicate(s) and subject device, Technology, including features, materials, and principles of operation.**

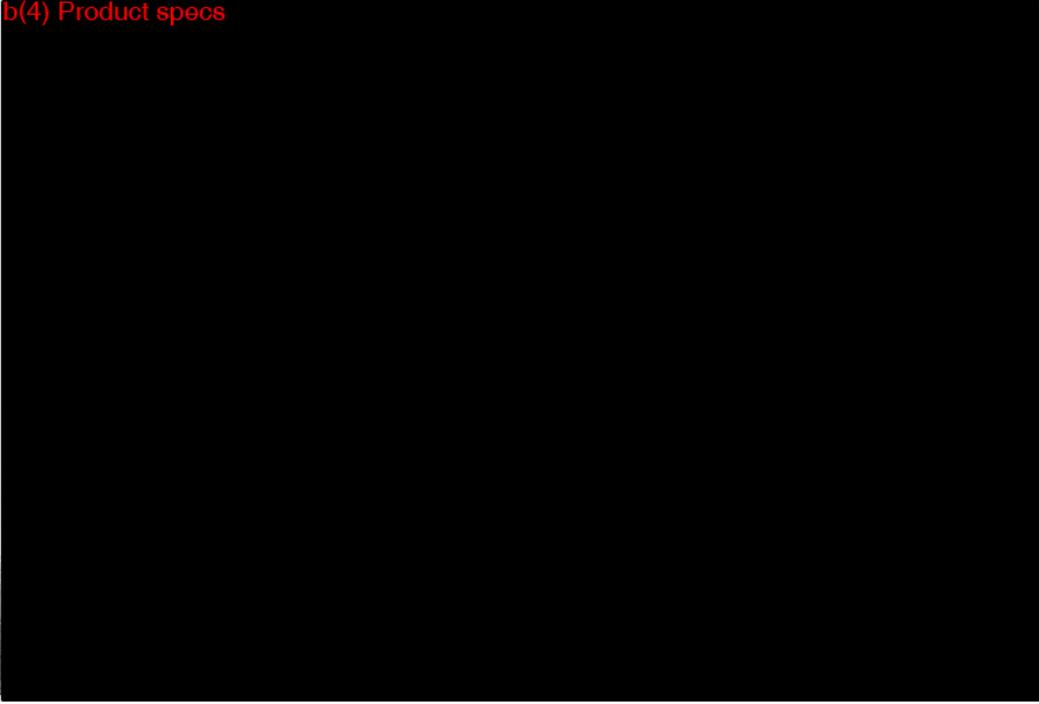
➤ The following table shows that each of these devices is similar as test results comparing these devices show similar results. The devices are so equivalent that the company follows standards that show us how to test this type of a device and the test results show the devices have the same performance and technological characteristics.

Function	DMRC Dual Cure Orthodontic Band Cement	Clear Aligner Adhesive /Band Lok (Reliance) (K123348)	Opal ®Band™ Cement (Opal Orthodontics) (K111696)
Sensitivity to Ambient Light	X	X	X
Depth of Cure	X	X	X
Flexural Strength (MPa)	X	X	X
Diametral Tensile Strength (MPa)	X	X	X
Vicker's Hardness	X	X	X
Shear Bond Strength on enamel (MPa)	X	X	X
Self-Cure Set Time (min)	X	X	X



- Composition of DMRC Dual Cure Orthodontic Band Cement:

b(4) Product specs



(Signature)

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200

San Ramon, CA 94583

Work Phone: 800/827-7940 Ext.212

Mobile Phone: 510-364-7842

Fax: 925/973-0764

Email: [dhua@daneng.com](mailto:dhua@daneng.com)



U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 10/28/2014

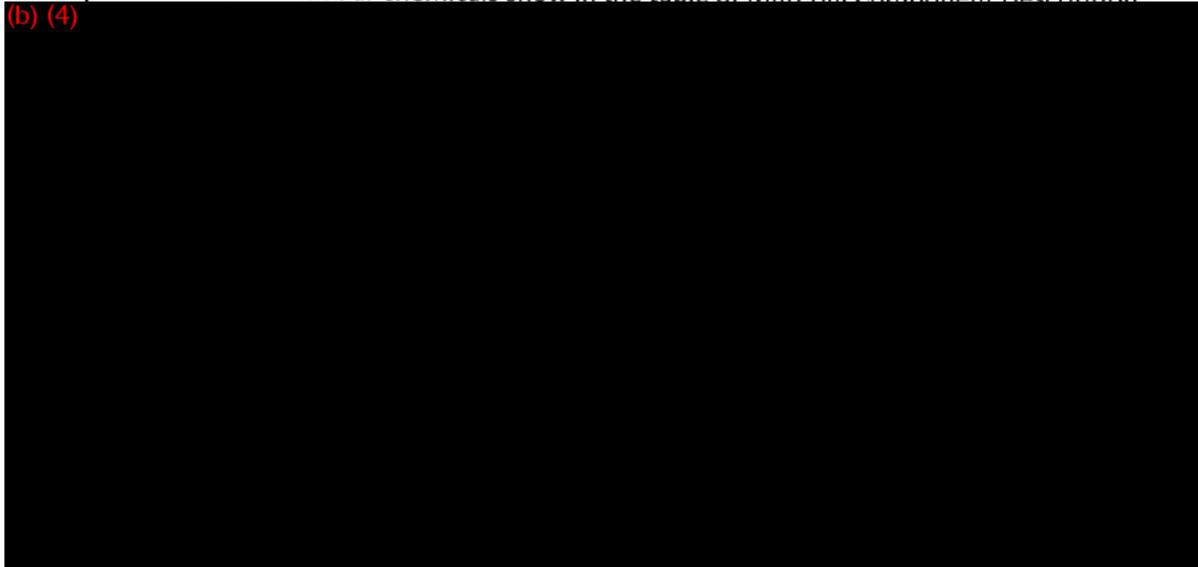
Subject: Response to K142881– Refuse To Accept (RTA) Checklist

**011\_Item 16 Analysis on the subject device and predicate**

*RTA - 16. Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)*

- An analysis of Chemical formulation in name, function and CAS number, both the subject device and predicate use the similar chemicals show in the table of Material Component Description:

(b) (4)



- Similarities in the Indications for Use:

Product	510(K)	Classification Name	Indications For Use
Clear Aligner Adhesive	K123348	Bracket Adhesive Resin and Tooth Conditioner	An orthodontic bonding adhesive for brackets and appliances to thermoplastic aligner surfaces
Opal <sup>®</sup> Band <sup>™</sup> Cement	K111696	Bracket Adhesive Resin and Tooth Conditioner	Uses chemical, light and glass ionomer polymerization to cement all types of orthodontic bands to the teeth
DMRC Dual Cure Orthodontic Band Cement	New (K142881)	Bracket Adhesive Resin and Tooth Conditioner	A two paste dual-cure adhesive intended for use as an orthodontic band cement for cementation of orthodontic bands



- The following table shows that each of these devices is similar as test results comparing these devices show similar results. The devices are so equivalent that the company follows standards that show us how to test this type of a device and the test results show the devices have the same performance and technological characteristics.

Function	DMRC Dual Cure Orthodontic Band Cement	Clear Aligner Adhesive /Band Lok (Reliance) (K123348)	Opal ®Band™ Cement (Opal Orthodontics) (K111696)
Sensitivity to Ambient Light	X	X	X
Depth of Cure	X	X	X
Flexural Strength (MPa)	X	X	X
Diametral Tensile Strength (MPa)	X	X	X
Vicker's Hardness	X	X	X
Shear Bond Strength on enamel (MPa)	X	X	X
Self-Cure Set Time (min)	X	X	X

- Summary of Safety and Effectiveness

DMRC Dual Cure Orthodontic Band Cement is a resin based material containing two paste dual-cure adhesive for cementation of orthodontic bands. The materials used in DMRC Dual Cure Orthodontic Band Cement are the same as used by our predicates, Reliance Orthodontic Product, Inc's Clear Aligner Adhesive (K123348), Opal ®Band™ Cement by Opal Orthodontics (K111696), and/or Band Lok which is the similar dental adhesive products. These materials have been widely used by numerous manufacturers in the medical/dental industry. Considering the safe history of our predicates, DMRC Dual Cure Orthodontic Band Cement is considered a safe medical device.

The efficacy or suitability to the intended purpose of DMRC Dual Cure Orthodontic Band Cement 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 DMRC Dual Cure Orthodontic Band Cement perform as well or better than the predicate devices currently on the market.

In conclusion, DMRC Dual Cure Orthodontic Band Cement has been designed and manufactured with the intended use and the product is compatible with a high level of protection of health and safety.

  
(Signature)

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200

San Ramon, CA 94583

Work Phone: 800/827-7940 Ext.212 Fax: 925/973-0764

Email: [dhua@daneng.com](mailto:dhua@daneng.com)

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 10/28/2014

Subject: Response to K142881– Refuse To Accept (RTA) Checklist

### 012\_Item 17 Proposed Labeling

***RTA – Submission does not include proposed package labels and labeling (e.g., instructions for use, package insert, operator’s manual) that include a description of the device, its intended use, and the directions for use***

***17a. Indications for use are not stated in labeling and are identical to Indications for Use form and 510(K) Summary (if 510(K) Summary provided)***

***17b. Submission does not include directions for use that  
- Indications for Use are not stated in labeling and are identical to Indications for Use form and 510(K) Summary (if 510(K) Summary provided)***

**Indications for use:**

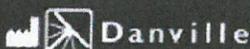
This device is a two paste dual-cure adhesive intended for use as an orthodontic band cement for cementation of orthodontic bands.

## **DMRC DUAL CURE ORTHODONTIC BAND CEMENT**

REF 60024

For Professional use only.  
U.S. Federal Law restricts this  
medical device to sell by or on  
order of a dentist.

Dental adhesive, Bracket & tooth  
conditioner Resin



DANVILLE MATERIALS, LLC  
SAN RAMON, CALIFORNIA 94583 USA  
PHONE 800/827-7940 FAX 925/973-0764



**MADE IN USA**

Store at or below 75°F (24°C)  
for at least 1 year.



**Danville**  
ENGINEERING & MATERIALS

[www.danvillematerials.com](http://www.danvillematerials.com)

3420 Fostoria Way Suite A-200

San Ramon, CA 94583 USA

**- includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D**

**DMRC Dual Cure**

ORTHODONTIC BAND CEMENT

REF 60024

5  
GM

 Danville



FAX 925/973-0764 800/827-7940

DANVILLE MATERIALS, LLC

MADE IN USA

LOT XXXXX

XXXX/XX

(Signature)

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200

San Ramon, CA 94583

Work Phone: 800/827-7940 Ext.212

Mobile Phone: 510-364-7842

Fax: 925/973-0764

Email: [dhua@daneng.com](mailto:dhua@daneng.com)



---

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 10/28/2014

Subject: Response to K142881– Refuse To Accept (RTA) Checklist

### **013\_Item 20 Statement on Device Specific Guidance**

There is not a device-specific guidance, and/or any special control guidance document, applicable to the device, the submission includes labeling to establish that submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.

---

(Signature)

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212  
Mobile Phone: 510-364-7842  
Fax: 925/973-0764

Email: [dhua@daneng.com](mailto:dhua@daneng.com)



U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 10/28/2014

Subject: Response to K142881– Refuse To Accept (RTA) Checklist

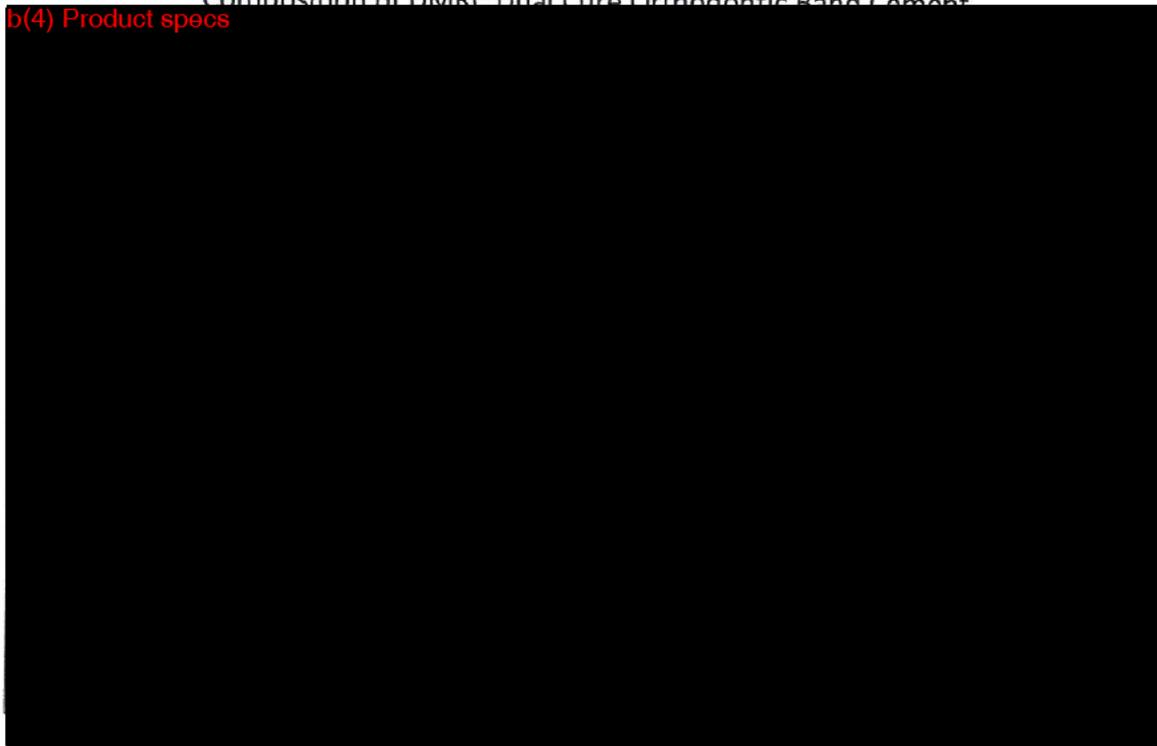
### **014\_Item 28 Statement on the summary of methods**

***RTA - 28. Submission does not include summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.***

DMRC Dual Cure Orthodontic Band Cement is a resin based material containing two paste dual-cure adhesive for cementation of orthodontic bands, the resin based material that has been widely used by numerous manufacturers in the medical/dental industry. Chemical raw materials are purchased from well established vendors, with the MSDS listed for major ingredients and their storage condition with shelf life indicated.

Composition of DMRC Dual Cure Orthodontic Band Cement

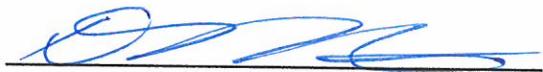
b(4) Product specs



The test methods used to establish that device performance demonstrate the efficacy or suitability to the intended purpose of DMRC Dual Cure Orthodontic Band Cement. The test methods and storage conditions are not expected to affect device safety or effectiveness.

In conclusion, DMRC Dual Cure Orthodontic Band Cement has been designed and manufactured with the intended use and the product is compatible with a high level of protection of health and safety.

**The summary of methods used to establish that device performance is not adversely affected by aging**



(Signature)

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212  
Mobile Phone: 510-364-7842  
Fax: 925/973-0764

Email: [dhua@daneng.com](mailto:dhua@daneng.com)



**Danville**  
ENGINEERING & MATERIALS

[www.danvillematerials.com](http://www.danvillematerials.com)  
3420 Fostoria Way Suite A-200  
San Ramon, CA 94583 USA

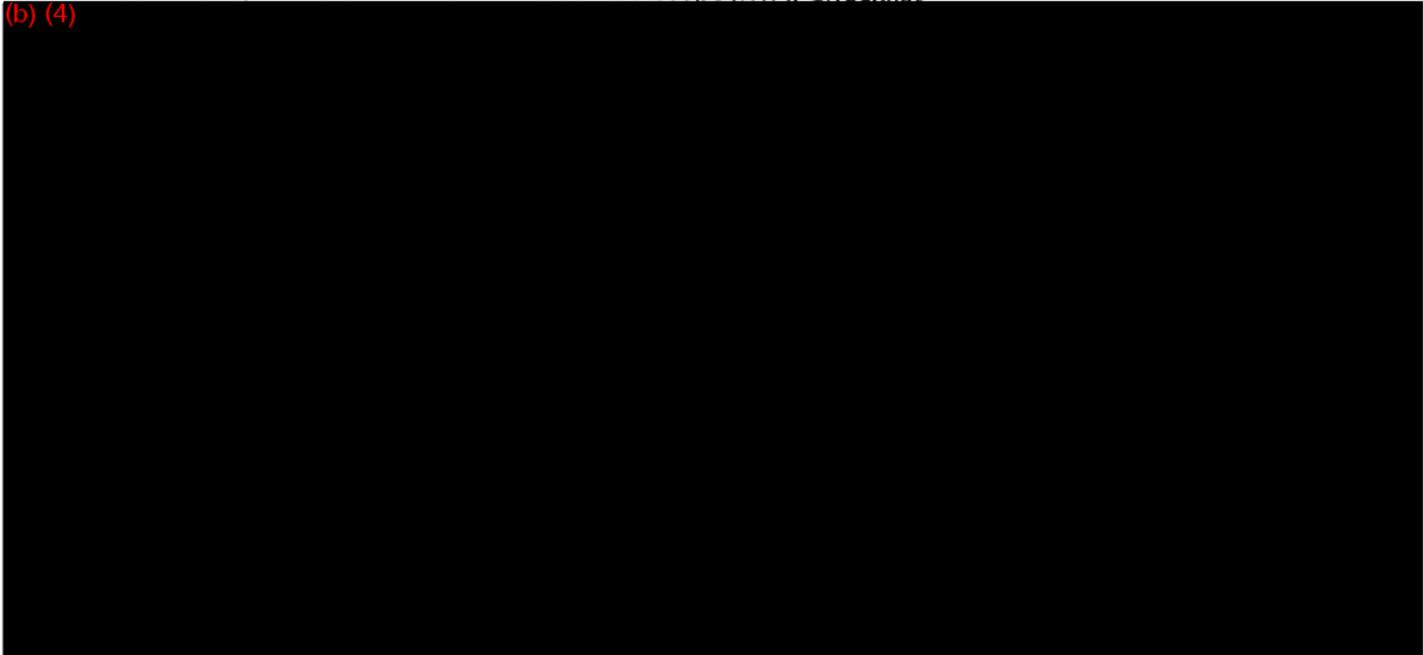
---

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 10/28/2014

Subject: Response to K142881– Refuse To Accept (RTA) Checklist

(b) (4)



(Signature)

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200

San Ramon, CA 94583

Work Phone: 800/827-7940 Ext.212

Mobile Phone: 510-364-7842

Fax: 925/973-0764

Email: [dhua@daneng.com](mailto:dhua@daneng.com)



K142881/S002

www.danvillematerials.com  
3420 Fostoria Way Suite A-200  
San Ramon, CA 94583 USA

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 01/13/2015

FDA CDRH DMC

JAN 15 2015

Subject: Response to K142881/S001 – Deficiencies on December 29, 2014

**001\_Cover Letter K142881/S001 Deficiencies Response**

Received

Dear FDA Officer,

Please review the following information for our response to the Deficiencies notification,

- A. FDA Notification:  
December 18, 2014 **K142881/S001 is being pending – Deficiencies Notification**  
**K142881/S001** is on Hold Pending Your Response (Attached Questions, 3 pages)
- B. Submission Number: **K142881/S001**  
Applicant: **Danville Materials LLC**  
Submitter: **Dong Hua**  
Device: **DMRC Dual Cure Orthodontic Band Cement**
- C. Table of Contents (Response to a deficiency letter as its own PDF file)

Item #	Item Description	Total Page#
001_Cover Letter	Cover Letter K142881/S001 Deficiencies Response	4
002_ Question 1 Response	510(K) Summary Revised	6
003_ Question 2 Response	Comparison of the Predicate and Subject device	4
004_ Question 3 Response	Comparison of the Indication for Use and IFU Revised	6
005_ Question 4 Response	Comparison of the Physical Testing	4
006_ Question 5 Response	Shelf Life Study	10
007_ Question 6 Response	Shelf Life Question	1
008_ Question 7 Response	Biocompatibility	6
009_ Question 8 Response	Performance Testing	1

If any additional information or clarification is required, please contact the undersigned at (925) 973-0710. Ext. 212

Sincerely yours,

Dong Hua

Regulatory Affair Director and QA Manager  
3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212  
Fax: 925/973-0764  
Email: [dhua@daneng.com](mailto:dhua@daneng.com)

1-05  
19

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 01/13/2015

Subject: Response to K142881/S001 – Deficiencies on December 29, 2014

**001\_Cover Letter K142881/S001 Deficiencies Response**

Dear FDA Officer,

Please review the following information for our response to the Deficiencies notification,

- A. FDA Notification:  
December 18, 2014 **K142881/S001 is being pending – Deficiencies Notification**  
**K142881/S001** is on Hold Pending Your Response (Attached Questions, 3 pages)
- B. Submission Number: **K142881/S001**  
Applicant: **Danville Materials LLC**  
Submitter: **Dong Hua**  
Device: **DMRC Dual Cure Orthodontic Band Cement**
- C. Table of Contents (Response to a deficiency letter as its own PDF file)

Item #	Item Description	Total Page#
001_Cover Letter	Cover Letter K142881/S001 Deficiencies Response	4
002_ Question 1 Response	510(K) Summary Revised	6
003_ Question 2 Response	Comparison of the Predicate and Subject device	4
004_ Question 3 Response	Comparison of the Indication for Use and IFU Revised	6
005_ Question 4 Response	Comparison of the Physical Testing	4
006_ Question 5 Response	Shelf Life Study	10
007_ Question 6 Response	Shelf Life Question	1
008_ Question 7 Response	Biocompatibility	6
009_ Question 8 Response	Performance Testing	1

If any additional information or clarification is required, please contact the undersigned at (925) 973-0710. Ext. 212

Sincerely yours,

  
Dong Hua

Regulatory Affair Director and QA Manager  
3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212  
Fax: 925/973-0764  
Email: [dhua@daneng.com](mailto:dhua@daneng.com)



**Dong Hua**

---

**From:** Phillip Woods [phillip.woods@fda.hhs.gov]  
**Sent:** Monday, December 29, 2014 12:53 PM  
**To:** Dong Hua  
**Cc:** Phillip Woods  
**Subject:** K142881/S001 is on Hold Pending Your Response  
**Attachments:** K142881.Deficiencies.AINN.pdf

December 29, 2014

We have reviewed your submission K142881/S001 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K142881/S001 to:

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf> for current information on the number of copies and the format (paper versus eCopy) you must submit.

Your response is due within 180 days from the date of this request, which is June 27, 2015. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Should you have questions about this email, you may contact Phillip Woods, the lead reviewer assigned to your submission.

\*\*\* This is a system-generated email notification \*\*\*



**Danville**  
ENGINEERING & MATERIALS

[www.danvillematerials.com](http://www.danvillematerials.com)

3420 Fostoria Way Suite A-200  
San Ramon, CA 94583 USA



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

K142881  
Danville Materials, LLC.  
DMRC Dual Cure Orthodontic Band Cement

Administrative Information

Deficiencies:

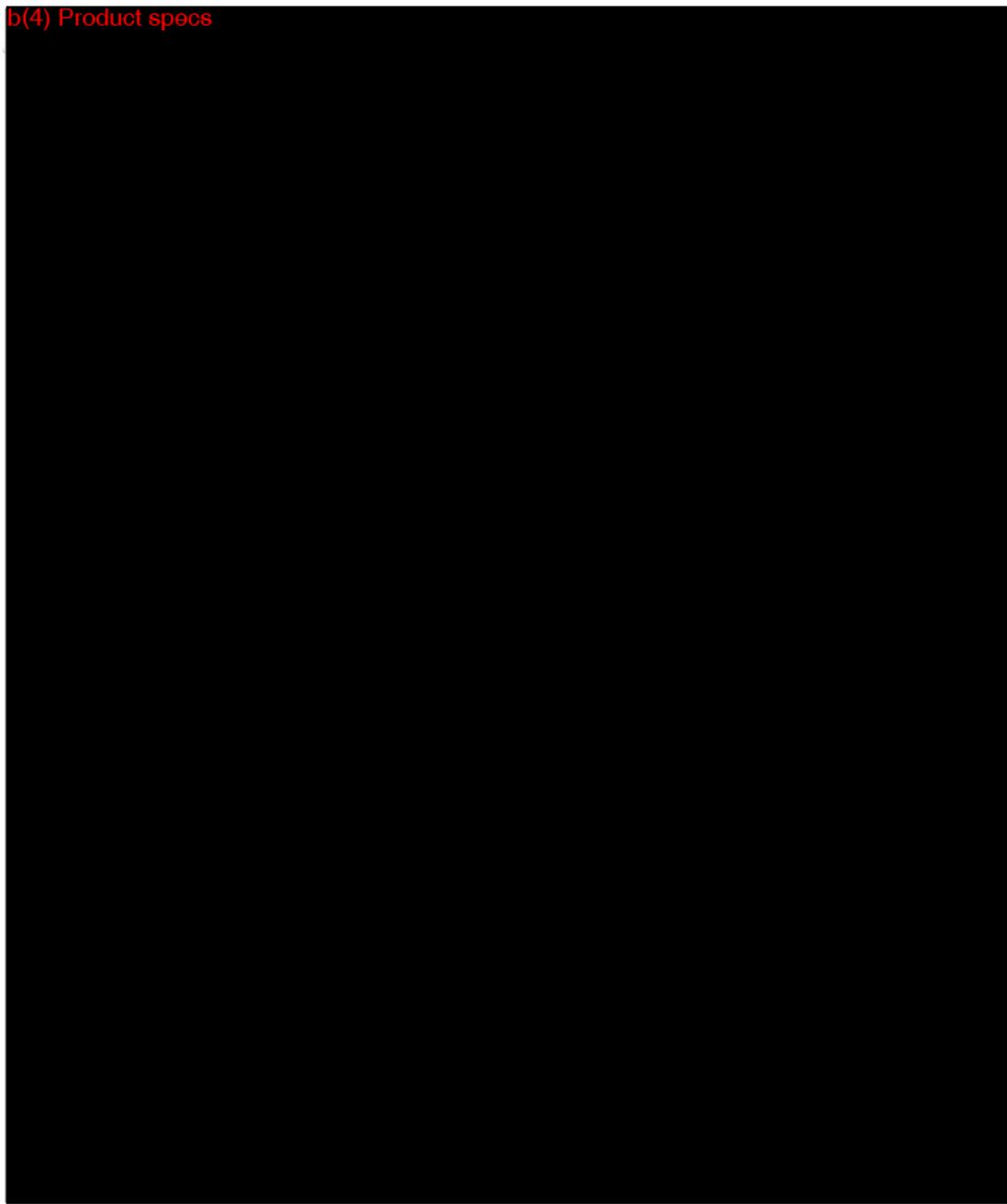


(b) (4)



Page 2 - Dong Hua

b(4) Product specs





---

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

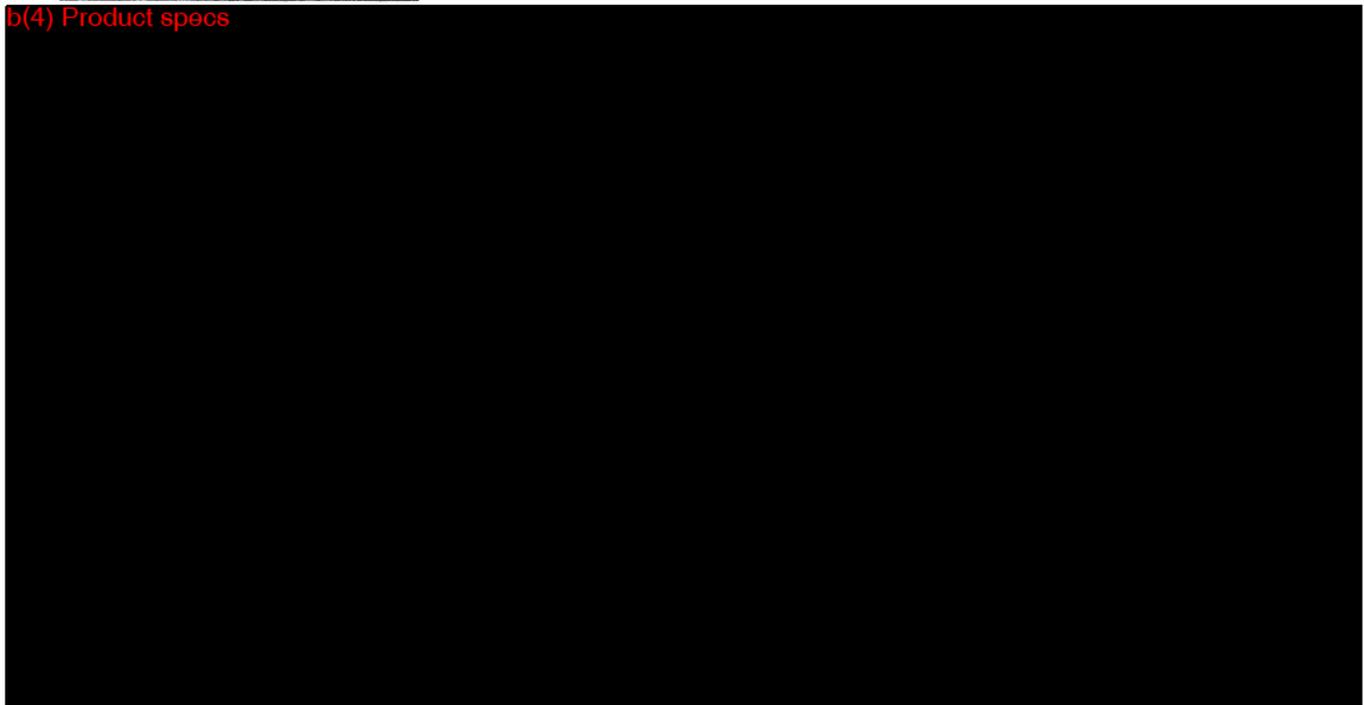
Date: 01/13/2015

Subject: Response to K142881/S001 – Deficiencies on December 29, 2014

**002\_Question 1 Response 510(K) Summary Revised**

**Administrative Information**

b(4) Product specs





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: January 13, 2015

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

- Trade/Proprietary Name: DMRC Dual Cure Orthodontic Band Cement
- 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 Devices to Which Substantial Equivalence (SE) is claimed:**

- **K073697** Transbond Supreme Adhesive By 3M Unitek

**D. Description of the Device:**

- Indication For Use: The DMRC Dual Cure Orthodontic Band Cement is a dual-cure adhesive intended for use as an orthodontic band cement for bonding of orthodontic bands to enamel
- Intended Use of the Device: The DMRC Dual Cure Orthodontic Band Cement is polymer based filling and restorative materials, it contains base and catalyst for dual curing process as orthodontic band cement. This product can be used for patients of all ages

**E. A comparison of the Transbond Adhesive Products by 3M Unitek and the DMRC Dual Cure Orthodontic Band Cement to determine SE:**

- **Table 1\_** Physical Properties of the DMRC Dual Cure Orthodontic Band Cement and 3M Transbond XT

The equivalence to the predicate device is supported by **Table 1** and the enclosures following:



Test Method	Std Ref.	Specification	DMRC Dual Cure Orthodontic Band Cement (K142881)	Notebook Ref	Transbond XT (3M) (K073697)	Notebook Ref (Lot:N291722)
Sensitivity to Ambient Light (9300 Lux)	ISO 4049	Homogeneous at 60 sec	Pass	132-154B	Fail	132-091B
Depth of Cure, mm (10sec @ 500mw/cm <sup>3</sup> ) (4mm x 12mm mold)	ISO 4049	≥ 1.5	2.2	132-079B	6.8	096-064A
Flexural Strength (MPa)	ISO 4049	≥ 80	95.6 (20.5)	132-079D	135.4 (13)	089-181A
Diametral Tensile Strength (MPa)	ADA Specification No. 27	NA	43.4 (6)	132-145F	53.1 (7)	132-074A
Shear Bond Strength on enamel (MPa) with E-Bond	Danville Test Method	NA	23.6 (7.2)	132-148B	10.3 (7.0)	132-182A
Shear Bond Strength on enamel (MPa) without E-Bond	Danville Test Method	NA	13.4 (5.6)	132-148A	27.8 (22.6)	134-182B
Shear Bond Strength on non-precious metal (Mpa) with E-Bond	Danville Test Method	NA	6.1 (6.8)	134-177A	5.6 (3.1)	134-179A
Shear Bond Strength on non-precious metal (Mpa) without E-Bond	Danville Test Method	NA	7.2 (3.5)	134-177B	0*	134-179B

\*Material debonded before data collecting, therefore SBS was determined to be 0 MPa

The DMRC Dual Cure Orthodontic Band Cement (**Table 1**) should be compared to the predicate material in terms of:

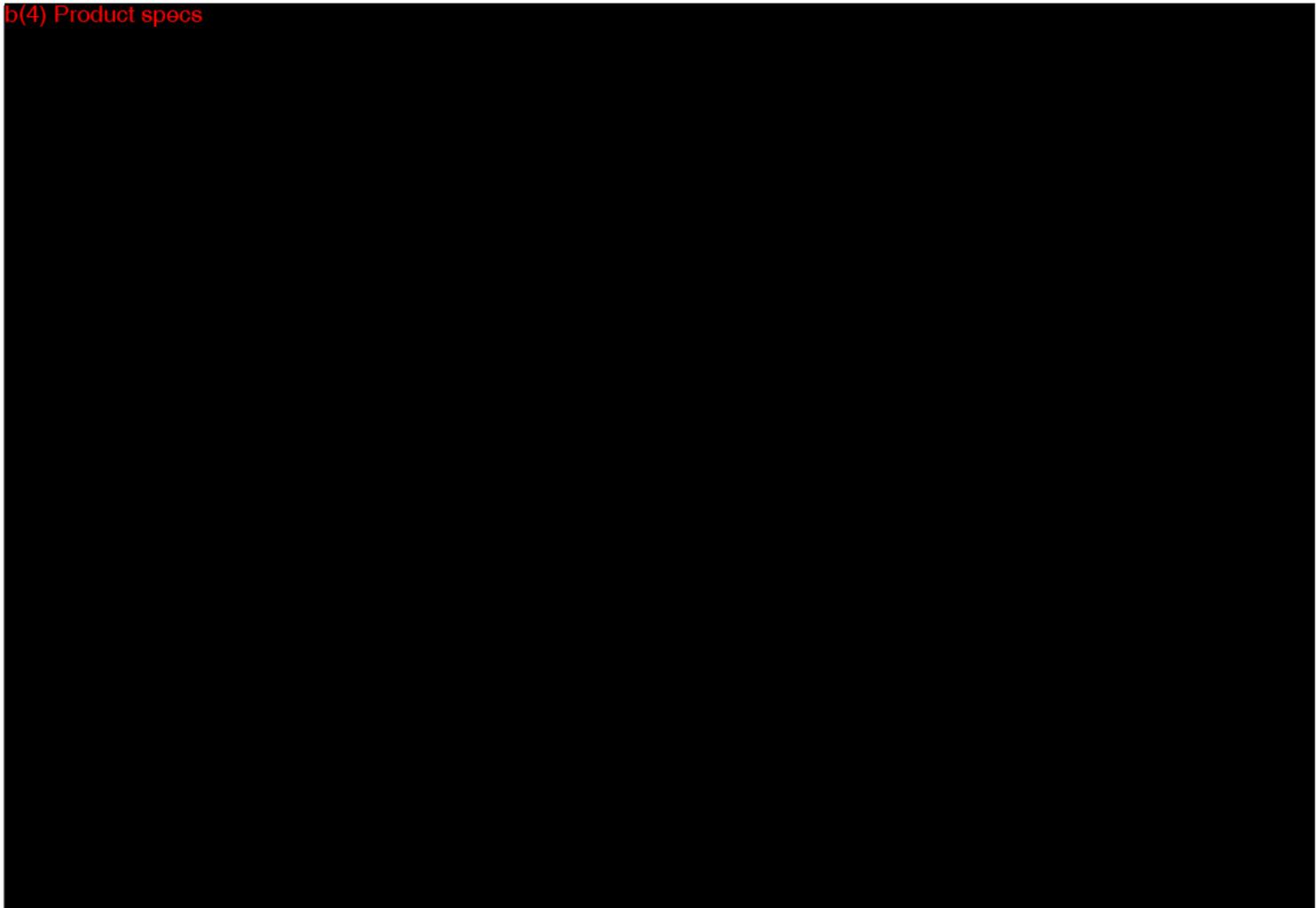
- Flexural Strength – ISO 4049, ≥ 80 Mpa
- Depth of Cure – ISO 4049, ≥ 1.5 mm
- Sensitivity to Ambient Light – ISO 4049, Homogeneous at 60 sec
- Additional property comparisons are also listed,
  - Ultradent bracket Shear Bond Strength (SBS) on Enamel that show equivalence to the predicate material
  - Ultradent bracket Shear Bond Strength (SBS) on non-precious metal that show equivalence to the predicate material

➤ Chemical Identity: **Table 2\_** Material Component Description

The name, function and CAS number of each component of the product is identified in,



b(4) Product specs



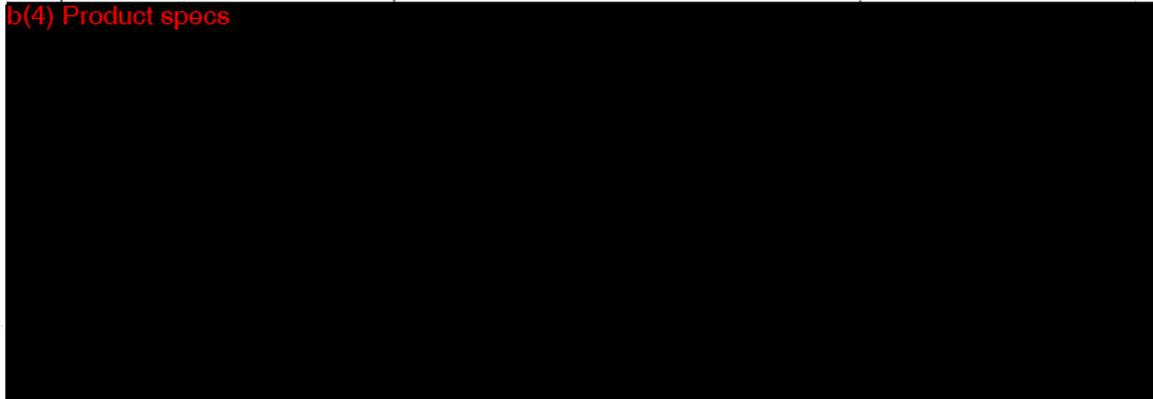
Chemical raw materials are purchased from well established vendors, the MSDS sheets on raw chemical materials in major ingredients is available.

The complete formulation for the product, identifying the individual chemical components by percentage to a sum of 100% is attached in **Table 3\_ Composition of DMRC Dual Cure Orthodontic Band Cement** which includes both base and catalyst

Product	Dual Cure Orthodontic Band Cement (Base & Catalyst)	Proposed 510K range
BisGMA	14.69	11.0 – 19.0
UDMA	3.69	3.0 – 9.0
TEGDMA	12.94	7.0 - 19.0
HEMA	5.63	5.0 – 12.0
EDMAB	0.14	0.10 – 0.30
CQ	0.06	0.05 – 0.15



b(4) Product specs



➤ Similarities in the Indications for Use:

Product	510(K) Number	Classification Name	Indications For Use
3M Unitek's Transbond Supreme Adhesive	K073697	Bracket Adhesive Resin and Tooth Conditioner	Light cure orthodontic adhesive designed for bonding brackets and other bondable appliances to etched enamel
DMRC Dual Cure Orthodontic Band Cement	New (K142881)	Bracket Adhesive Resin and Tooth Conditioner	A dual-cure adhesive intended for use as an orthodontic band cement for bonding of orthodontic bands to enamel

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

DMRC Dual Cure Orthodontic Band Cement is a resin based material containing a dual-cure adhesive for cementation of orthodontic bands. The materials used in DMRC Dual Cure Orthodontic Band Cement are the same as used by our predicates, Transbond Supreme Adhesive By 3M Unitek (K073697), which is the similar dental adhesive products; The raw chemical materials have been widely used by numerous manufacturers in the medical/dental industry.

All testing performed on the DMRC Dual Cure Orthodontic Band Cement was derived from the risk assessment which evaluated the effects of the feature changes. The efficacy or suitability to the intended purpose of DMRC Dual Cure Orthodontic Band Cement 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 DMRC Dual Cure Orthodontic Band Cement performs as well or better than the predicate devices currently on the market.

Discussion of Clinical Tests performed: N/A

F. **Summary of Risk/Benefit Review:**

Considering the safe history of our predicates, Transbond Supreme Adhesive By 3M Unitek (K073697), DMRC Dual Cure Orthodontic Band Cement is considered a safe medical device. Our



**Danville**  
ENGINEERING & MATERIALS

**[www.danvillematerials.com](http://www.danvillematerials.com)**

3420 Fostoria Way Suite A-200  
San Ramon, CA 94583 USA

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 subject device, DMRC Dual Cure Orthodontic Band Cement 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 Dual Cure Orthodontic Band Cement is compatible with a high level of protection of health and safety and may be released to the market.

If any additional information or clarification is required, please contact the undersigned at (925) 973-0710. Ext. 212

Sincerely yours,

A handwritten signature in blue ink, appearing to be 'Dong Hua', written over a horizontal line.

(Signature)

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200

San Ramon, CA 94583

Work Phone: 800/827-7940 Ext.212

Fax: 925/973-0764

Email: [dhua@daneng.com](mailto:dhua@daneng.com)

---

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 01/13/2015

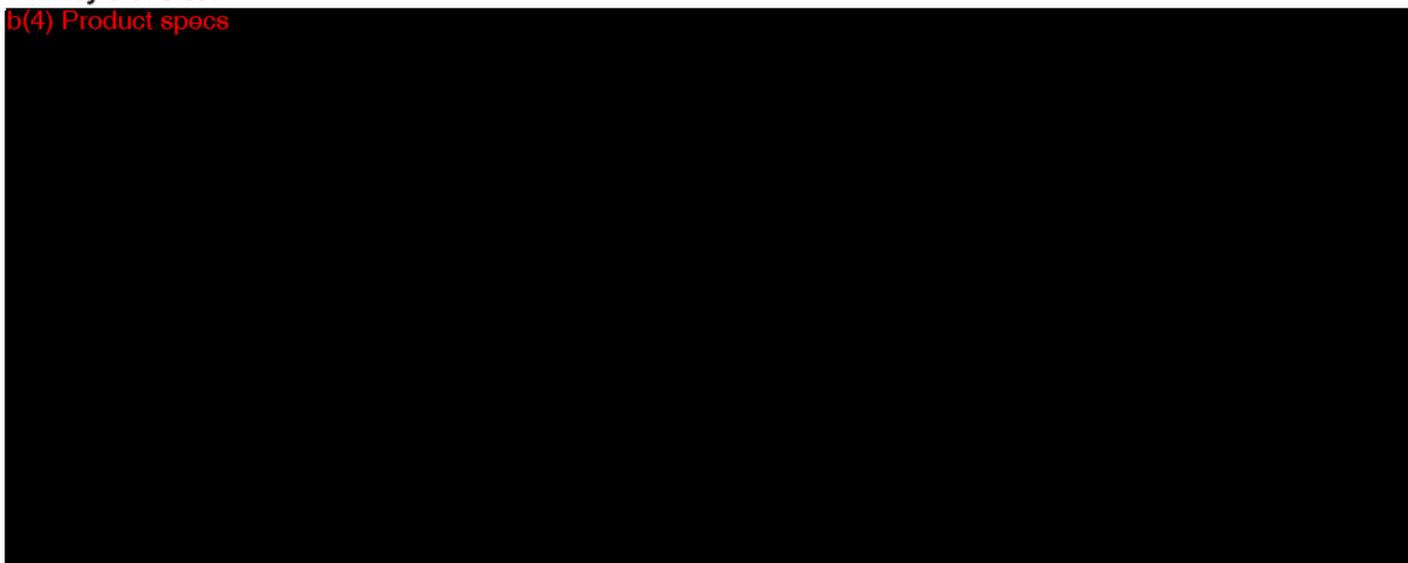
Subject: Response to K142881/S001 – Deficiencies on December 29, 2014

**003\_Question2 Response Comparison of the Predicate and Subject device**

**Administrative Information**

**Deficiencies:**

b(4) Product specs

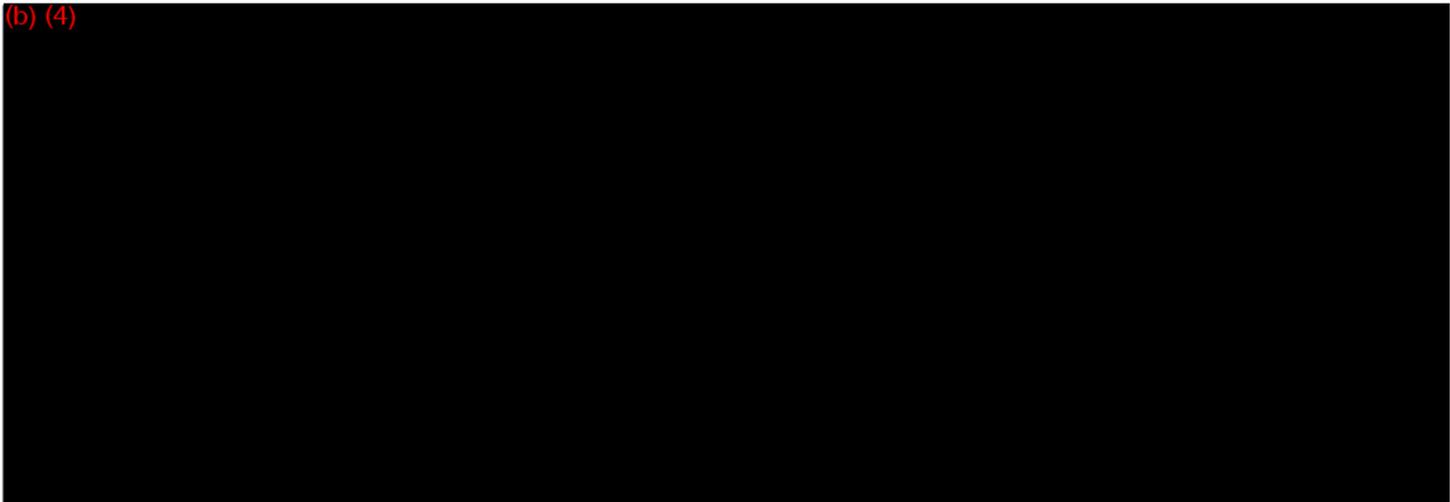


**Legally Marketed Predicate Devices to Which Substantial Equivalence (SE) is claimed:**

- **K073697** Transbond Supreme Adhesive By 3M Unitek

**A comparison of the Clear Aligner Adhesive By Reliance Orthodontic Products, Inc and the DMRC Dual Cure Orthodontic Band Cement to determine SE:**

- **Table 1**\_Physical and Mechanical Properties: The DMRC Dual Cure Orthodontic Band Cement vs. 3M Transbond XT



\*Material debonded before data collecting; therefore SBS was determined to be 0 MPa

The DMRC Dual Cure Orthodontic Band Cement (**Table 1**) should be compared to the predicate material in terms of:

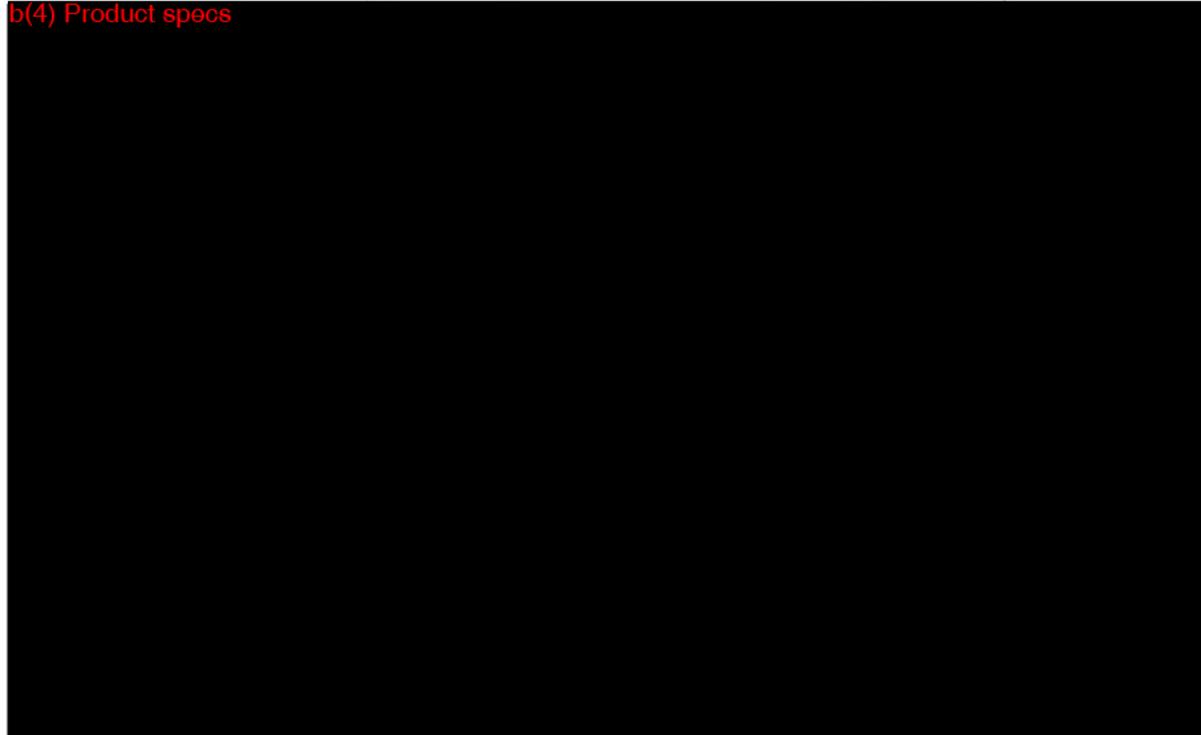
- Flexural Strength – ISO 4049,  $\geq 80$  Mpa
  - Depth of Cure – ISO 4049,  $\geq 1.5$  mm
  - Sensitivity to Ambient Light – ISO 4049, Homogeneous at 60 sec
  - Additional property comparisons are also listed,
    - Ultradent bracket Shear Bond Strength (SBS) on Enamel that show equivalence to the predicate material
    - Ultradent bracket Shear Bond Strength (SBS) on non-precious metal that show equivalence to the predicate material
- **Table 2**\_The following table shows that the proposed device is similar as test results comparing the predicate device show similar results. The devices are so equivalent that the company follows standards that show us how to test this type of a device and the test results show the devices have the same performance and technological characteristics.



Function	DMRC Dual Cure Orthodontic Band Cement (K142881)	Transbond XT (3M) (K073697)
Sensitivity to Ambient Light	X	-
Depth of Cure	X	X
Flexural Strength (MPa)	X	X
Diametral Tensile Strength (MPa)	X	X
Shear Bond Strength on enamel (MPa)	X	X
Shear Bond Strength on non-precious metal (Mpa)	X	X

➤ **Table 3\_** Composition of DMRC Dual Cure Orthodontic Band Cement. The complete formulation for the product containing both base and catalyst, identifying the individual chemical components by percentage to a sum of 100% in 510(K) Summary

b(4) Product specs



DMRC Dual Cure Orthodontic Band Cement is a resin based material containing catalysis and base dual-cure adhesive for cementation of orthodontic bands. The materials used in DMRC Dual Cure Orthodontic Band Cement are the similar dental adhesive products used by our predicates, Transbond Supreme Adhesive By 3M Unitek (K073697). The raw chemical materials have been widely used by numerous manufacturers in the medical/dental industry.



**Danville**  
ENGINEERING & MATERIALS

**[www.danvillematerials.com](http://www.danvillematerials.com)**

3420 Fostoria Way Suite A-200  
San Ramon, CA 94583 USA

If any additional information or clarification is required, please contact the undersigned at (925) 973-0710. Ext. 212

Sincerely yours,

A handwritten signature in blue ink, appearing to read 'Dong Hua', written over a horizontal line.

(Signature)

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200

San Ramon, CA 94583

Work Phone: 800/827-7940 Ext.212

Fax: 925/973-0764

Email: [dhua@daneng.com](mailto:dhua@daneng.com)

---

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 01/13/2015

Subject: Response to K142881/S001 – Deficiencies on December 29, 2014

**004\_Question 3 Response Comparison of the Indication for Use and IFU Revised**

**Device Description**

**Deficiency:**

(b) (4)



**Legally Marketed Predicate Devices to Which Substantial Equivalence (SE) is claimed:**

- **K073697** Transbond Supreme Adhesive By 3M Unitek
- FDA Form 3881 Indications for Use Statement
- A comparison of the following for the predicate(s) and subject device, Indications for Use:

Product	510(K) Number	Classification Name	Indications For Use
3M Unitek's Transbond Supreme Adhesive	K073697	Bracket Adhesive Resin and Tooth Conditioner	Light cure orthodontic adhesive designed for bonding brackets and other bondable appliances to etched enamel
DMRC Dual Cure Orthodontic Band Cement	New (K142881)	Bracket Adhesive Resin and Tooth Conditioner	A dual-cure adhesive intended for use as an orthodontic band cement for bonding of orthodontic bands to enamel

- The revised summary of the Traditional 510(K) substantial equivalence information can be found in the 002\_Question 1 Response 510(K) Summary Revised
- The revised Instruction For Use

If any additional information or clarification is required, please contact the undersigned at (925) 973-0710. Ext. 212

Sincerely yours,



(Signature)

Dong Hua  
Regulatory Affair Director and QA Manager  
3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212  
Fax: 925/973-0764  
Email: [dhua@daneng.com](mailto:dhua@daneng.com)



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

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

**Indications for Use**

510(k) Number (if known)  
K142831

Device Name

DMRC Dual Cure Orthodontic Band Cement

Indications for Use (Describe)

DMRC Dual Cure Orthodontic Band Cement is a dual-cure adhesive intended for use as an orthodontic band cement for bonding of orthodontic bands to enamel

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:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

*"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."*



## Instructions for Use

### DMRC Dual Cure Orthodontic Band Cement

#### Indication For Use

The DMRC Dual Cure Orthodontic Band Cement is a dual-cure adhesive intended for use as an orthodontic band cement for bonding of orthodontic bands to enamel

#### **Application**

- Step 1.** Lightly roughen the inside of the band with a fine diamond bur or microetcher.
- Step 2.** Prophyl, rinse, dry and isolate tooth to be banded. Acid etching of the enamel is not required for cementing bands, however, it will increase strength required for high stress appliances.
- Step 3.** Remove the cap from the syringe (do not re-use the cap). Install the mixing tip into the syringe.
- Step 4.** Extrude the needed amount of material directly to the band then seat band and clean off excess flash.
- Step 5.** At this point you have three curing options:
  - a) With a dental curing light, cure the cement from the occlusal surface for 20 seconds. Cement can be exposed to saliva at this point. Final cure will occur in 5 minutes.
  - b) With a dental curing light, cure the cement from the occlusal surface for 50 seconds. Cement is now completely cured and can be exposed to headgear forces immediately.
  - c) Allow the cement to chemically cure on its own; complete polymerization will occur in 10 minutes.

#### **Precautions and Warnings**

Uncured resin material can cause irritation. Wash hands after handling material. The bonded materials are formulated to be used at room temperature. Shelf life is two years when handled properly.

Do not store materials in the proximity to eugenol-containing products.

Do not expose materials to elevated temperatures or intense light.

Etchant contains 38% phosphoric acid which is harmful to skin and eyes. In case of eye contact, flush with water and seek immediate medical assistance.

Store at 72°F (22°C).

#### **SECTION I - IDENTIFICATION**

Company Name: Danville Materials

3420 Fostoria Way Suite A-200

San Ramon, CA 94583

Phone (800) 827-7940

Fax: (925) 973-0764

Prepared: September 24, 2014



## SECTION II – HAZORD(S) IDENTIFICATION



Flammable - Keep away from sources of ignition.

Irritant-Irritating to eyes and skin; may cause sensitization by skin contact. Refer to Section 15 for specific Risk-and-Safety-phrases.

## SECTION III - COMPOSITION/INFORMATION ON INGREDIENTS

Name	CAS Number	%
Dental Glass Filler		30-80
Bisphenol A glycidyl methacrylate	1565-94-2	5-80

## SECTION IV: FIRST-AID MEASURES

Skin: Wash off affected area with soap and water.

Ingestion: Seek immediate medical advice, carry container with label.

Eyes: Rinse immediately with plenty of water and seek medical advice.

## SECTION V: FIRE-FIGHTING MEASURES

Flash Point: >+104°C

Extinguishing Media: Carbon Dioxide, Foam, Dry Chemical

Special Fire Fighting Procedures: None

Flammable Limits: NA

Unusual Fire and Explosion Hazards: None

## SECTION VI: ACCIDENTAL RELEASE MEASURES

NONE

## SECTION VII: HANDLING AND STORAGE

This product is used exclusively for dental purposes by trained personnel. Avoid high light intensity ambient light (>10000 lux).

Keep ignition source away – Do not smoke.

Store away from oxidizing agents.

Store away from reducing agents.

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

## SECTION VIII: EXPOSURE CONTROLS/PERSONAL PROTECTION

Eye Protection: Use protective eyewear.

Hand Protection: Use protective gloves.

Respiratory Protection: Avoid prolonged breathing of vapors of uncured material.

Skin Protection: Use any necessary hygiene measures.

## **SECTION IX: PHYSICAL AND CHEMICAL PROPERTIES**

Vapor Pressure mm HG: NA

Soluble Boiling Point: NA

Vapor Density (Air = 1): NA

Appearance: Packable material

Evaporation Rate (Ether = 1): NA

Odor: None

% Volatile by Volume: NA

## **SECTION X: STABILITY AND REACTIVITY**

Stability: Stable

Conditions to avoid: Prolonged extreme heat and free radical indicators

Incompatibility: (Materials to avoid) Contact with iron

Hazardous Decomposition Products: None

Hazardous Polymerization: None

## **SECTION XI: TOXICOLOGICAL INFORMATION**

NONE

## **SECTION XII: ECOLOGICAL INFORMATION**

N/A

## **SECTION XIII: DISPOSAL CONSIDERATIONS**

Refer to any community provisions relating to waste. In their absence, refer to national or regional provisions relating to waste.

## **SECTION XIV: TRANSPORT INFORMATION**

Stable under normal conditions of use, transportation, and storage.

## **SECTION XV: REGULATORY INFORMATION**

Classification:F-Flammable, R11-Highly flammable, Xi-Irritant, R36 -Irritating to eyes, R38-Irritating to skin, R43-May cause sensitization by skin contact.

Safety:S(2) 7-16-26-28 Keep out of the reach of children. Keep container tightly closed. Keep away from sources of ignition-No smoking. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of soap and water.

## **SECTION XVI: OTHER INFORMATION**

None



---

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 01/13/2015

Subject: Response to K142881/S001 – Deficiencies on December 29, 2014

**005\_Question4 Response Comparison of the Physical Testing**

**Device Description**

**Deficiency:**

(b) (4)





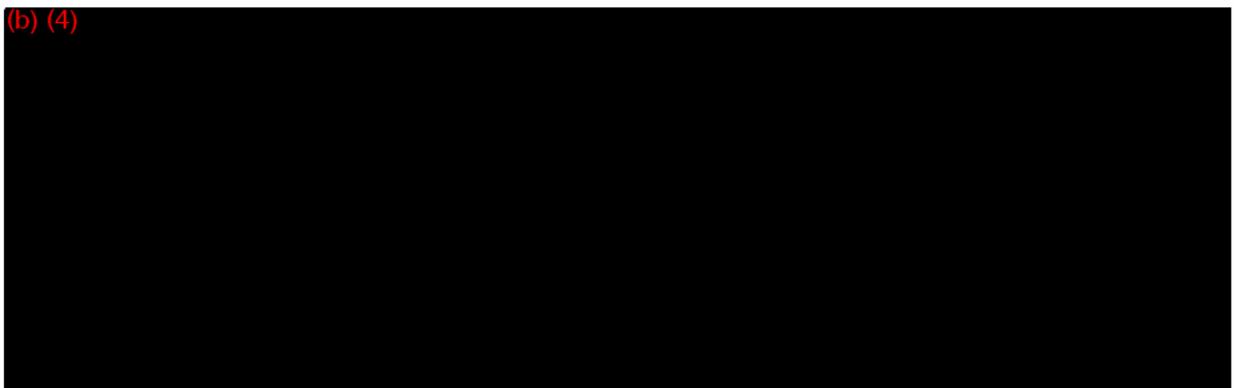
➤ **Selecting Performance Tests:**

(b) (4)



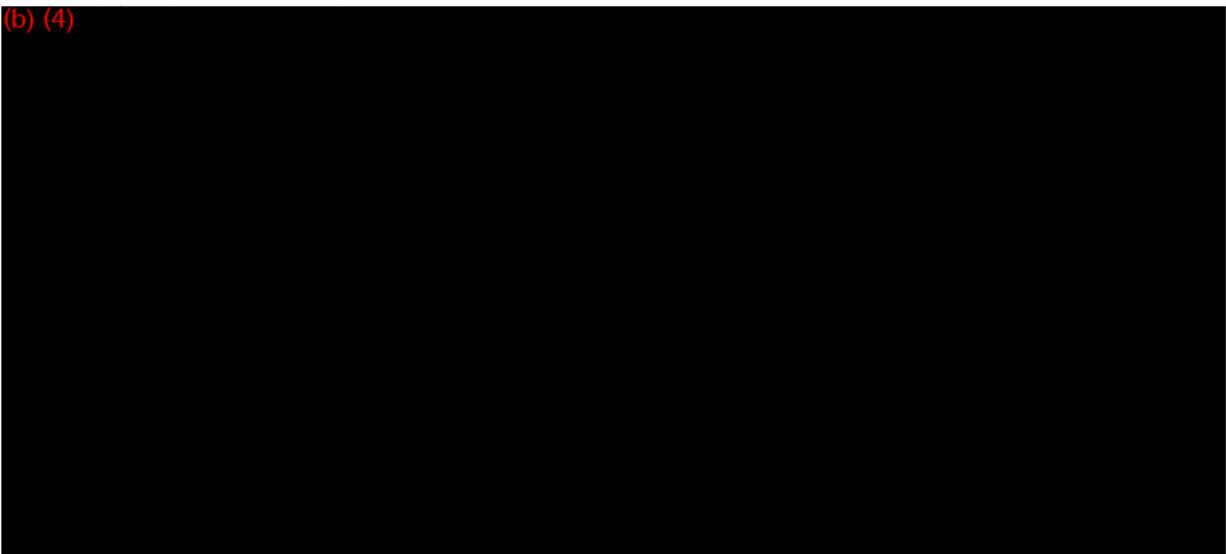
➤ **Objective of the additional tests:**

(b) (4)



➤ **Description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria,**

(b) (4)



(b) (4)

➤ *Results summary, conclusions,*

**Table 1.** Physical and Mechanical Properties: The DMRC Dual Cure Orthodontic Band Cement vs. 3M Transbond XT

(b) (4)

➤ *Brief Summary of the testing conducted*

(b) (4)

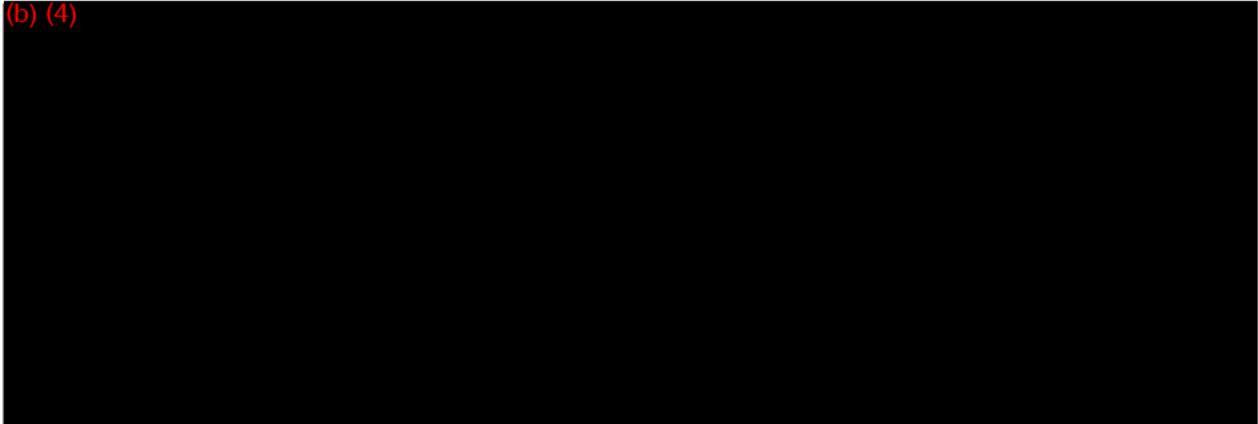


**Danville**  
ENGINEERING & MATERIALS

[www.danvillematerials.com](http://www.danvillematerials.com)

3420 Fostoria Way Suite A-200  
San Ramon, CA 94583 USA

(b) (4)



If any additional information or clarification is required, please contact the undersigned at (925) 973-0710. Ext. 212

Sincerely yours,



(Signature)

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200

San Ramon, CA 94583

Work Phone: 800/827-7940 Ext.212

Fax: 925/973-0764

Email: [dhua@daneng.com](mailto:dhua@daneng.com)



**Danville**  
ENGINEERING & MATERIALS

[www.danvillematerials.com](http://www.danvillematerials.com)  
3420 Fostoria Way Suite A-200  
San Ramon, CA 94583 USA

---

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

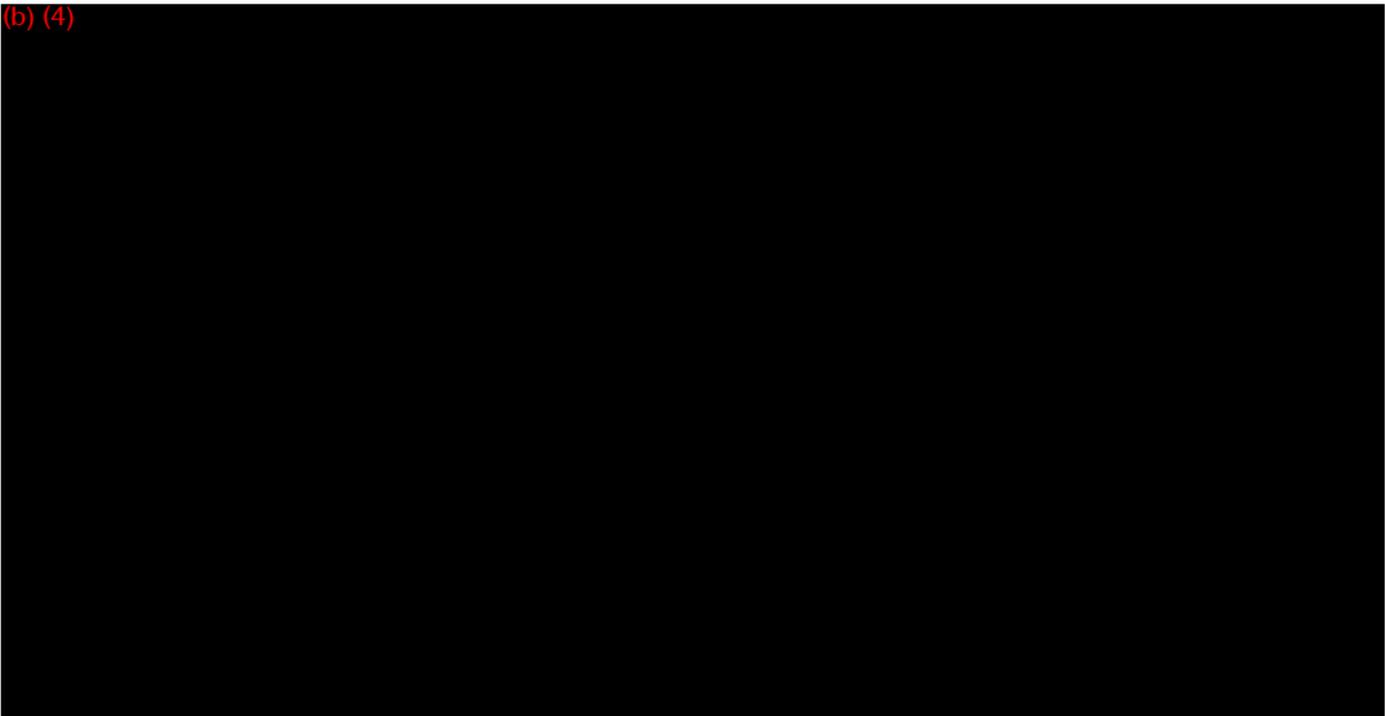
Date: 01/13/2015

Subject: Response to K142881/S001 – Deficiencies on December 29, 2014

**006\_Question 5 Response Shelf Life Study**

**Cleaning, Sterilization, Shelf-Life and/or Reuse**  
**Deficiency:**

(b) (4)





➤ Summary:

(b) (4)

➤ Preparation and Methods:

b(4)

➤ Results:

b(4)

➤ Conclusion:

b(4)

If any additional information or clarification is required, please contact the undersigned at (925) 973-0710. Ext. 212

Sincerely yours,

(Signature)

Dong Hua  
Regulatory Affair Director and QA Manager  
3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212  
Fax: 925/973-0764 Email: [dhua@daneng.com](mailto:dhua@daneng.com)



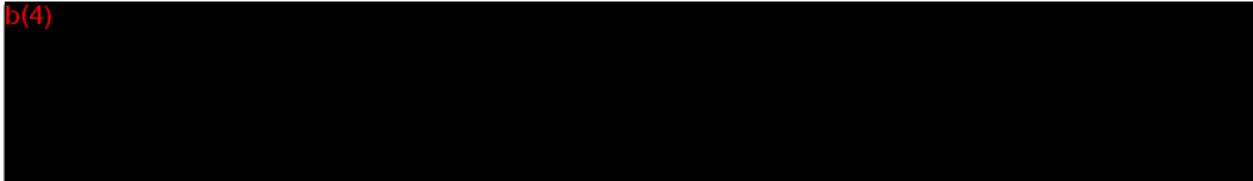
## Memorandum

**To:** Band Cement Product Design File  
**CC:** Product Development Group  
**From:** Kyle Ujemura *[Signature]*  
**Date:** December 19, 2014 *12/19/14*  
**Re:** SP0100 Band Cement at 3 months at 37°C - Interim Report

---

### Summary

b(4)



### Preparation and Methods

b(4)



### Results

b(4)

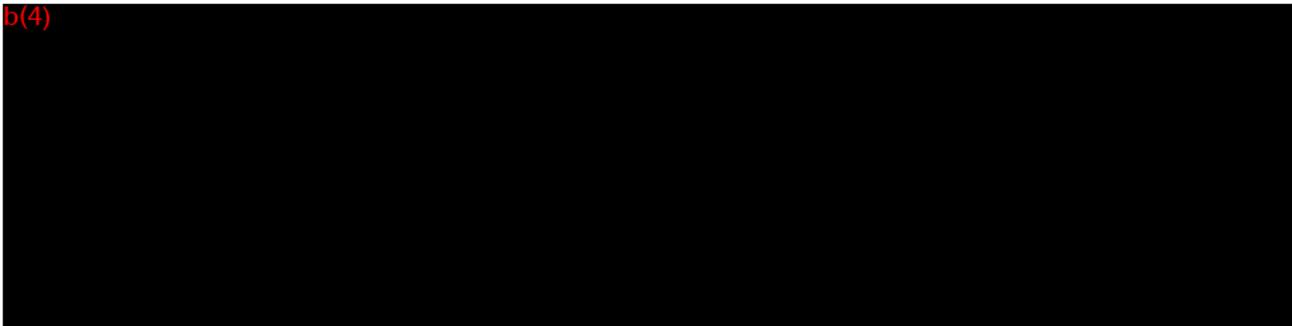




Table 1 SP0100 Bond Current Stability Data at 210°C - 1

b(4)

Table 1 SP0100 Bond Current Stability Data at 210°C - 2

b(4)















U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

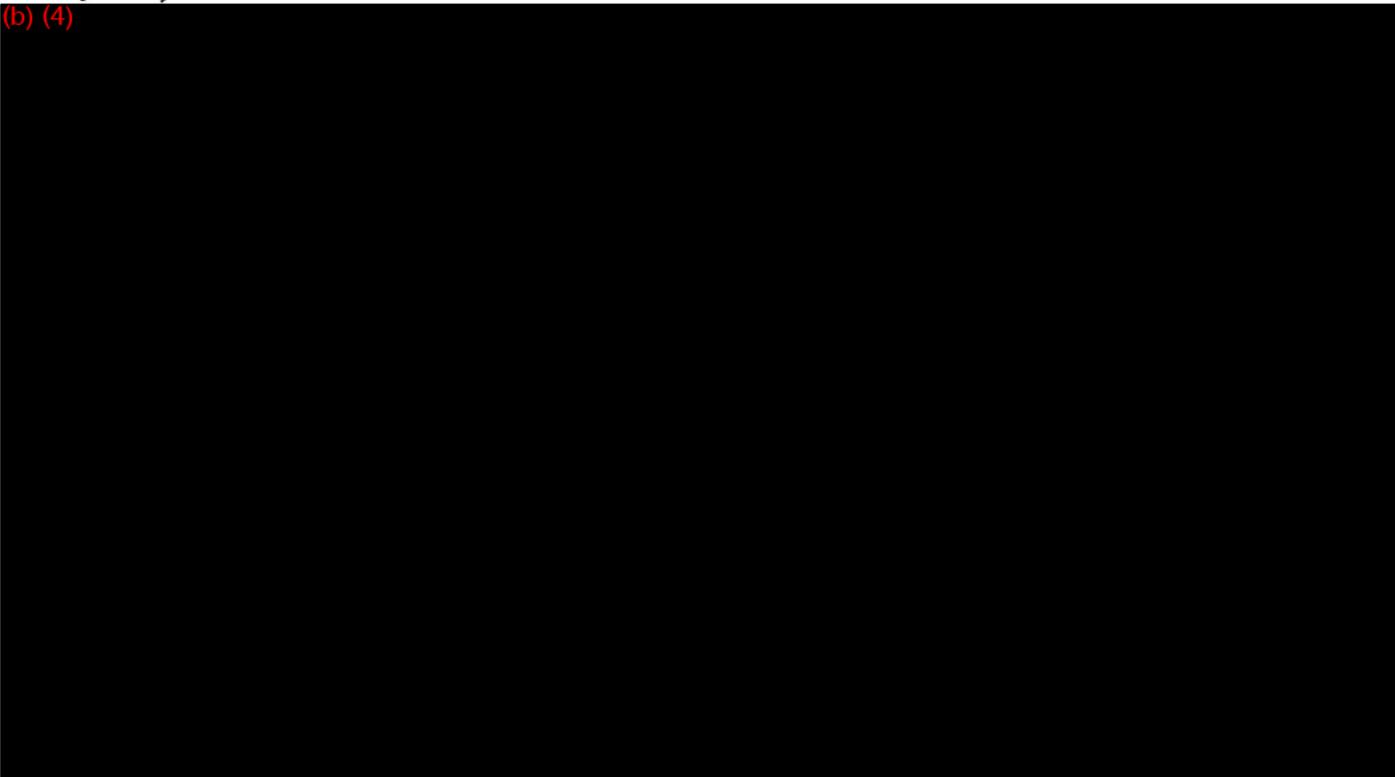
Date: 01/13/2015

Subject: Response to K142881/S001 – Deficiencies on December 29, 2014

**007\_ Question6 Response Shelf Life Question**

**Cleaning, Sterilization, Shelf-Life and/or Reuse**  
**Deficiency:**

(b) (4)



If any additional information or clarification is required, please contact the undersigned at (925) 973-0710. Ext. 212

Sincerely yours,



(Signature)

Dong Hua  
Regulatory Affair Director and QA Manager  
3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212  
Fax: 925/973-0764 Email: [dhua@daneng.com](mailto:dhua@daneng.com)

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 01/13/2015

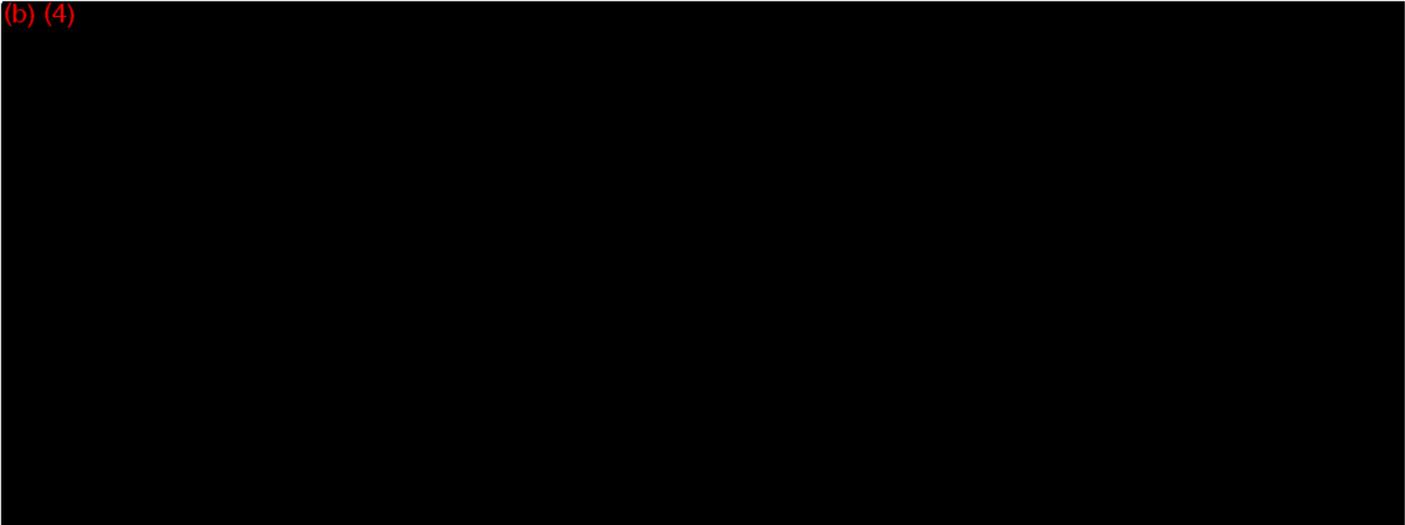
Subject: Response to K142881/S001 – Deficiencies on December 29, 2014

**008\_ Question7 Response Biocompatibility**

**Biocompatibility**

**Deficiency:**

(b) (4)



If any additional information or clarification is required, please contact the undersigned at (925) 973-0710. Ext. 212

Sincerely yours,

  
\_\_\_\_\_  
(Signature)

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200

San Ramon, CA 94583

Work Phone: 800/827-7940 Ext.212

Fax: 925/973-0764

Email: [dhua@daneng.com](mailto:dhua@daneng.com)







Department of Health and Human Services Food and Drug Administration <b>STANDARDS DATA REPORT FOR 510(k)s</b> (To be filled in by applicant)		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE <sup>1</sup> ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity ISO 10993-1: 2009 Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing within a risk management process		
<b>Please answer the following questions</b>		
	Yes	No
Is this standard recognized by FDA <sup>2</sup> ? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number <sup>3</sup> .....	#2-153, #2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests? .....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup> ? .....	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard? .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k? .....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Title of guidance: <u>FDA Draft Guidance "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices</u>		
<small> <sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]                     </small>		
<small> <sup>2</sup> Authority [21 U.S.C. 360d], <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</a> </small>		
<small> <sup>3</sup> <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a> </small>		
<small> <sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and                     </small>		
<small>                     address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.                 </small>		
<small> <sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a> </small>		
<small> <sup>6</sup> The online search for CDRH Guidance Documents can be found at <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</a> </small>		



EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity ISO 10993-1: 2009 Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing within a risk management process		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
This section applies only to requirements of the Paperwork Reduction Act of 1995.		
<b>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</b>		
<p>The burden time for this collection of information is estimated to average 1 hour 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:</p> <p style="margin-left: 40px;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov</p> <p style="margin-left: 40px;"><i>"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 control number."</i></p>		

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Date: 01/13/2015

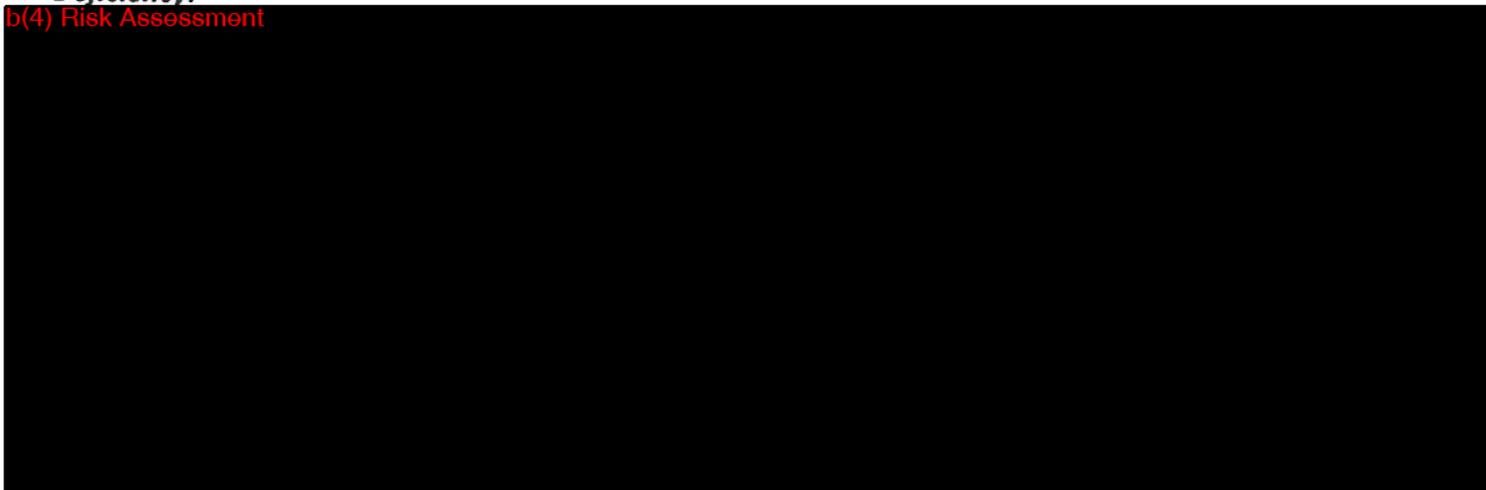
Subject: Response to K142881/S001 – Deficiencies on December 29, 2014

**009\_ Question 8 Response Performance Testing**

**Performance Testing**

**Deficiency:**

b(4) Risk Assessment



Sincerely yours,



(Signature)

Dong Hua

Regulatory Affair Director and QA Manager

3420 Fostoria Way, Suite A-200  
San Ramon, CA 94583  
Work Phone: 800/827-7940 Ext.212  
Fax: 925/973-0764 Email: [dhua@daneng.com](mailto:dhua@daneng.com)