

K153753

Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228

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Donna.Hartnett@ivoclarvivadent.com



December 23, 2015

FDA CDRH DMC

DEC 29 2015

Received

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

RE: 510(K) Pre-Market Notification – TelioCAD Multi
User Fee Identification no. (b)(4) Proprietary Information

To Whom It May Concern:

This is to notify you of our intent to market a new product called Telio CAD Multi. Telio CAD Multi are PMMA discs used for the fabrication of long-term temporaries by means of CAD/CAM technology. The device is described further in Section 9 – Device Description section of this submission

Below are the requirements for your review.

Classification Name:	Dental
Category:	Crown and Bridge, Temporary, Resin
Code Number:	76EBG
CFR Regulation:	872.3770
Common/Usual Name:	Temporary crown and bridge resin
Proprietary Name:	Telio CAD Multi
Est. Registration #:	1316092
Classification:	II

Type of application: X Traditional Abbreviated

Indications for Use:

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays

100

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Substantial Equivalence:

ZCAD Temp Esthetic (K132937) by Harvest Dental (Brea, CA)

Is the Device intended for prescription use?	Y
Is the device intended for over the counter use?	N
Does the device contain components derived from a tissue or other biologic source?	N
Is the device provided sterile?	N
Is the device intended for single use?	Y
Is the device reprocessed single use device?	N
If yes, does this device type require reprocessed validation data?	n/a
Does the device contain a drug?	N
Does the device contain a biologic?	N
Does the device use software?	N
Does the submission include clinical information?	N
Is the device implanted?	N
Is the device an In Vitro Diagnostic Device?	N

Prior submissions: There were no prior submissions to the FDA concerning this device.

EMC Testing: The device is not electrical in nature and therefore, no EMC testing is required.

Guidance Document There are no FDA Guidance Documents related to this type of device.

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

If you have any further questions concerning this submission, please feel free to contact me directly at (716) 691-0010 extension 2260.

The secondary points of contact are Martina Monaco and Maria Bertola.

Sincerely,

A handwritten signature in black ink, appearing to read 'DMH', written over a light blue horizontal line.

Donna Marie Hartnett
Director QA/Regulatory Affairs

Cc: Device Master File

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Proprietary Information 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		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) IVOCAR VIVADENT INC 175 PINEVIEW DRIVE ANHERST NY 14228 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****7874	2. CONTACT NAME Donna Hartnett 2.1 E-MAIL ADDRESS donna.hartnett@ivoclarvivadent.com 2.2 TELEPHONE NUMBER (include Area code) 716-691-2260 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 716-691-2294	
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> ☒ Premarket notification(510(k)); except for third party ☐ 513(g) Request for Information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ 30-Day Notice		
3.1 Select a center ☒ CDRH ☐ CBER 3.2 <u>Select one of the types below</u> ☒ Original Application <u>Supplement Types:</u> ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 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:		
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
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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) Proprietary
Information

02-Nov-
2015

Form FDA 3601 (05/13)

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

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December 23, 2015

U.S. Food and Drug Administration*
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RE: 510(K) Pre-Market Notification – TelioCAD Multi
User Fee Identification no. (b)(4) Proprietary
Information

To Whom It May Concern:

This is to notify you of our intent to market a new product called Telio CAD Multi. Telio CAD Multi are PMMA discs used for the fabrication of long-term temporaries by means of CAD/CAM technology. The device is described further in Section 9 – Device Description section of this submission

Below are the requirements for your review.

Classification Name:	Dental
Category:	Crown and Bridge, Temporary, Resin
Code Number:	76EBG
CFR Regulation:	872.3770
Common/Usual Name:	Temporary crown and bridge resin
Proprietary Name:	Telio CAD Multi
Est. Registration #:	1316092
Classification:	II

Type of application: X Traditional Abbreviated

Indications for Use:

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays

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Substantial Equivalence:

ZCAD Temp Esthetic (K132937) by Harvest Dental (Brea, CA)

Is the Device intended for prescription use?	Y
Is the device intended for over the counter use?	N
Does the device contain components derived from a tissue or other biologic source?	N
Is the device provided sterile?	N
Is the device intended for single use?	Y
Is the device reprocessed single use device?	N
If yes, does this device type require reprocessed validation data?	n/a
Does the device contain a drug?	N
Does the device contain a biologic?	N
Does the device use software?	N
Does the submission include clinical information?	N
Is the device implanted?	N
Is the device an In Vitro Diagnostic Device?	N

Prior submissions: There were no prior submissions to the FDA concerning this device.

EMC Testing: The device is not electrical in nature and therefore, no EMC testing is required.

Guidance Document There are no FDA Guidance Documents related to this type of device.

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

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The secondary points of contact are Martina Monaco and Maria Bertola.

Sincerely,

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Donna Marie Hartnett
Director QA/Regulatory Affairs

Cc: Device Master File

Indications for Use

510(k) Number (if known)

Device Name
TelioCAD Multi

Indications for Use (Describe)

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(K) SUMMARY

TelioCAD Multi



Contact: Donna Marie Hartnett

Company: Ivoclar Vivadent, Inc.
175 Pineview Drive, Amherst, NY 14228
+716-691-0010

Date Prepared: December 23, 2015

Proprietary Name: **Telio® CAD Multi**

Classification Name: Crown and Bridge, Temporary, Resin (872.3770)
(Classification Code EBG)

Device Description: Telio CAD Multi are PMMA discs used for fabrication of long-term temporaries by means of CAD/CAM technology. The PMMA discs have a Long-term (12-month) wear period and durable shade stability with lifelike layered appearance. The device is available in 8 shades (BL2, A1, A2, A3, A3.5, A4, B1 and B2) and 4 thicknesses 12mm, 16mm, 20mm and 25mm. They are the standard 98.5 mm in diameter to permit use with the Wieland Select Milling equipment or other equipment which accepts 98.5 mm discs. The material exhibits high homogeneity due to industrial manufacturing process and temporaries can be easily reproduced using the CAD/CAM Technology. The device is contraindicated for use in permanent restorations and bridge designs involving more than two adjacent pontics. The device should not be used in patients with para-functional habits, ex. Bruxism or patients known to be allergic to the ingredients.

Indications for Use:

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays

Predicate Device: ZCAD Temp Esthetic (K132937) by Harvest Dental (Brea,CA)

Comparison to predicate device: The predicate device to which Telio CAD Multi has been compared is ZCAD Temp Esthetic (K132937). For this application, Telio CAD Multi has been compared to its predicate with regard to chemical composition, performance data, principles of operation and Instructions for Use and indications for use. The comparison shows that Telio CAD Multi is substantially equivalent to the predicate device.

510(K) SUMMARY

TelioCAD Multi



Testing Summary: The subject device was not tested for Biocompatibility as no new elements are used in the chemical composition as compared to the predicate device. Biocompatibility evaluation was carried out according to ISO 10993-1 and ISO 7504. No changes have been made which will affect biocompatibility. The device was tested according to ISO 10477:2004 Dentistry – Polymer based crown and bridge materials for Surface finish, Flexural Strength, Bond strength, Water Sorption, Solubility, Shade Consistency and Color stability and the device met all requirements of the standard. The devices was also tested according to ISO 20795-1 :2013 Dentistry – Base Polymers – Part 1: Denture Base Polymers for5 Modulus of Elasticity and Residual monomer and the device met these requirements. Finally, testing according to ISO 179-1:2010 for Charpy toughness, ISO 180:2000 for izod impact strength and ISO 868:2003 for Vickers Hardness (converted from Shore D), was conducted to provide additional insight as to the properties of the materials for its intended use.

Conclusion: The above data and analysis demonstrates that Telio®CAD Multi is substantially equivalent to the predicate device.

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Pre-market Notification

Truthful and Accurate Statement (21 CFR 807.87(J))

I certify that, in my capacity as Director QA/Regulatory Affairs of Ivoclar Vivadent, Inc., I believe to the best of my knowledge, that all data and information submitted in the pre-market notification are truthful and accurate and that no material fact has been omitted.

Sincerely,

A handwritten signature in black ink, appearing to read 'DMH', with a long horizontal line extending to the right.

Donna Marie Hartnett
Ivoclar Vivadent, Inc.
Director QA/Regulatory Affairs

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 ¹

ISO 15223-1:2012 2d Edition Medical Devices - Symbols to be used with medical device labels, labelling and information

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number³ #5-90

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

Is a summary report ⁴ 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) ⁵? ☐ ☐

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 ⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510k? ☐ ☐

Title of guidance: _____

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

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

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

⁴ 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.

⁵ 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>

⁶ 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 15223-1:2012 2d Edition Medical Devices - Symbols to be used with medical device labels, labelling and information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER All	SECTION TITLE	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED [♣]		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED [♣]		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ 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.

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Department of Health and Human Services
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TYPE OF 510(K) SUBMISSION



Traditional



Special



Abbreviated

STANDARD TITLE ¹

ISO 10477:2004 2d Edition Dentistry - Polymer based crown and bridge materials

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number³ #4-126

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

Is a summary report ⁴ 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)⁵? ☒ ☐

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 ⁶ that is associated with this standard?..... ☒ ☐
If yes, was the guidance document followed in preparation of this 510k? ☒ ☐

Title of guidance: Dental Composite Resin Devices - Premarket Notification Submissions October 26, 2005

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

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

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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.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10477:2004 2d Edition Dentistry - Polymer based crown and bridge materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2.3, 2.3	Sensitivity to ambient light and depth of cure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

The device cannot be classified under the standard and these sections were not applicable to the device

DESCRIPTION

Elements that were tested included Flexural Strength, Bond Strength, Water sorption, Solubility, Shade consistency and colour stability.

JUSTIFICATION

The standard does not specifically apply to the subject device as the standard excludes devices intended for use posterior regions. However, the standard contains elements for material verification of single attributes which help to prove effectiveness.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ 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.

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE ¹

ISO 10993-1:2009, Biological evaluation of medical devices - Part 1

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number ³ #2-156

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

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

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

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

Title of guidance: FDA Bluebook Memorandum G95-1 Use of International Standard ISO 10993

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

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-1:2009, Biological evaluation of medical devices - Part 1

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER All	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED [‡]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED [‡]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ 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.

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Rockville, MD 20850

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION



Traditional



Special



Abbreviated

STANDARD TITLE ¹

ISO 179-1:2010 Plastics - Determination of Charpy impact properties - Part 1: Non-instrumented impact test

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?



FDA Recognition number³ #

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



Is a summary report ⁴ 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) ⁵?



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 ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?



Title of guidance:

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

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

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⁴ 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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 179-1:2010 Plastics - Determination of Charpy impact properties - Part 1: Non-instrumented impact test

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

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TYPE OF 510(K) SUBMISSION



Traditional



Special



Abbreviated

STANDARD TITLE ¹

ISO 180:2000/A1:2006 Plastics - Determination of izod impact strength

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?



FDA Recognition number³ #

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



Is a summary report ⁴ 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?.....
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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.



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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 180:2000/A1:2006 Plastics - Determination of izod impact strength

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * 		
DESCRIPTION 		
JUSTIFICATION 		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * 		
DESCRIPTION 		
JUSTIFICATION 		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * 		
DESCRIPTION 		
JUSTIFICATION 		

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TYPE OF 510(K) SUBMISSION



Traditional



Special



Abbreviated

STANDARD TITLE ¹

ISO 20795-1:2013 2d Edition Dentistry - Base Polymers - Part 1: Denture Base Polymers

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?



FDA Recognition number³ #

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



Is a summary report ⁴ 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) ⁵?



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



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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 20795-1:2013 2d Edition Dentistry - Base Polymers - Part 1: Denture Base Polymers

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 5.2.9/5.2.13	SECTION TITLE Flexural Modulus & Residual monomer	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * The Standard is applicable to Denture Base Polymers which the subject device is NOT. The device was only tested for Flexural Modulus and Residual Monomer and no further testing was performed.		
DESCRIPTION Test Methodology per the Standard was followed.		
JUSTIFICATION There is no Standard application to the subject device. Flexural Modulus and Residual Monomer were determined to be the most applicable criteria to test.		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE ¹

ISO 7405:2008 Second Edition Dentistry: Evaluation of Biocompatibility of medical devices used in dentistry

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number ³ #4-179

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

Is a summary report ⁴ 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) ⁵? ☐ ☐

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 ⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510k? ☐ ☐

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier]
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² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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STANDARD TITLE

ISO 7405:2008 Second Edition Dentistry: Evaluation of Biocompatibility of medical devices used in dentistry

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED [‡]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED [‡]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED [‡]

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION



Traditional



Special



Abbreviated

STANDARD TITLE ¹

ISO 868:2003 3rd Edition Plastics and ebonite - Determination of indentation hardness by means of a durometer

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?



FDA Recognition number³ #

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



Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?



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STANDARD TITLE

ISO 868:2003 3rd Edition Plastics and ebonite - Determination of indentation hardness by means of a durometer

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
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		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
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JUSTIFICATION		

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8 - Executive Summary

The purpose of this application is to seek marketing clearance of TelioCAD Multi.

TelioCAD Multi is a line of 98.5 mm PMMA discs for use in milling machines with an appropriate disc holder for milling temporary and long term temporart (up to 12 months) dental restorations.

The device is delivered in a non-sterile state and is not intended to be sterilized by the user. This is customary in dentistry and is similar to the predicate device.

INDICATIONS FOR USE

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays

The PMMA discs have a Long-term (12-month) wear period and durable shade stability with lifelike layered appearance. The device is available in 8 shades (BL2, A1, A2, A3, A3.5, A4, B1 and B2) and 4 thicknesses 12mm, 16mm, 20mm and 25mm. They are the standard 98.5 mm in diameter to permit use with the Wieland Select Milling equipment or other equipment which accepts 98.5 mm discs. The material exhibits high homogeneity due to industrial manufacturing process and temporaries can be easily reproduced using the CAD/CAM Technology.

(b)(4) Proprietary Information

[REDACTED]. The device is identical to the predicate device by Harvest ZCAD (510K K132937) and the VIPI Block (K102341). The only difference is that the TelioCAD Multi disc is polished on both sides to differentiate. Polishing has no impact on the safety and effectiveness of the device and only improves esthetics of the delivered device.

The device was tested in accordance with ISO 10477:2004 for Polymer based crown and bridge materials and meets the requirements. Summary reports are included in this submission.

This submission provides sufficient evidence that TelioCAD Multi is substantially equivalent to the predicate device.

9 – DEVICE DESCRIPTION

Telio CAD Multi consists of polymer (PMMA) blocks for the fabrication of long-term temporaries using CAD/CAM technology. The discs include fluorescent particles to give the appearance of multi layering for a more favorable esthetic result in the final restoration. Telio CAD Multi restorations are either milled in the dental practice utilizing a chairside design/milling system or in the dental laboratory. The restorations can be polished quickly and efficiently before insertion.

INDICATIONS FOR USE

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays

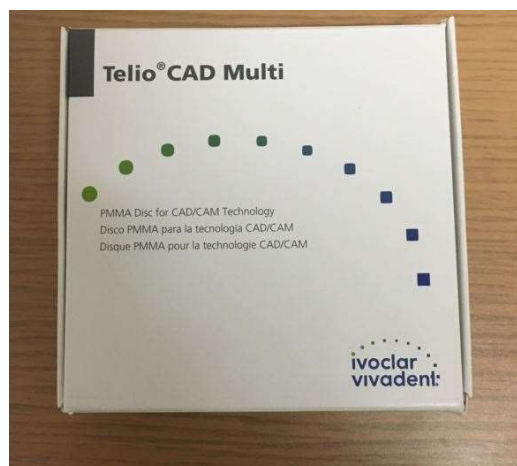
The PMMA discs have a Long-term (12-month) wear period and durable shade stability with lifelike layered appearance. The device is available in 8 shades (BL2, A1, A2, A3, A3.5, A4, B1 and B2) and 4 thicknesses 12mm, 16mm, 20mm and 25mm. They are the standard 98.5 mm in diameter to permit use with the Wieland Select Milling equipment or other equipment which accepts 98.5 mm discs. The material exhibits high homogeneity due to industrial manufacturing process and temporaries can be easily reproduced using the CAD/CAM Technology.

The device is contraindicated for use in permanent restorations and bridge designs involving more than two adjacent pontics. The device should not be used in patients with para-functional habits, ex. Bruxism or patients known to be allergic to the ingredients.

The discs are sold as single units, packaged in a cardboard box with protective foam. They are labeled with an RFID label in order for the milling machine (equipment with a reader) to identify thickness and shade. The RFID label includes the relevant identification information, diameter, height and shade, as well as an “UP” arrow for proper insertion into the milling unit.

9 – DEVICE DESCRIPTION

Top View Box:



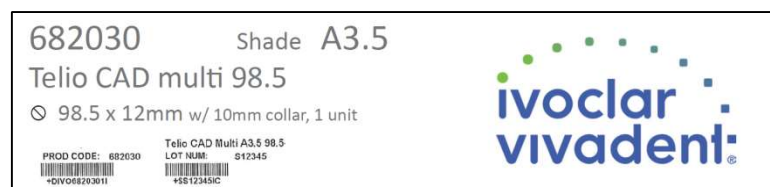
Full Box Detail:



Side labeling on disc



Barcode on side of box

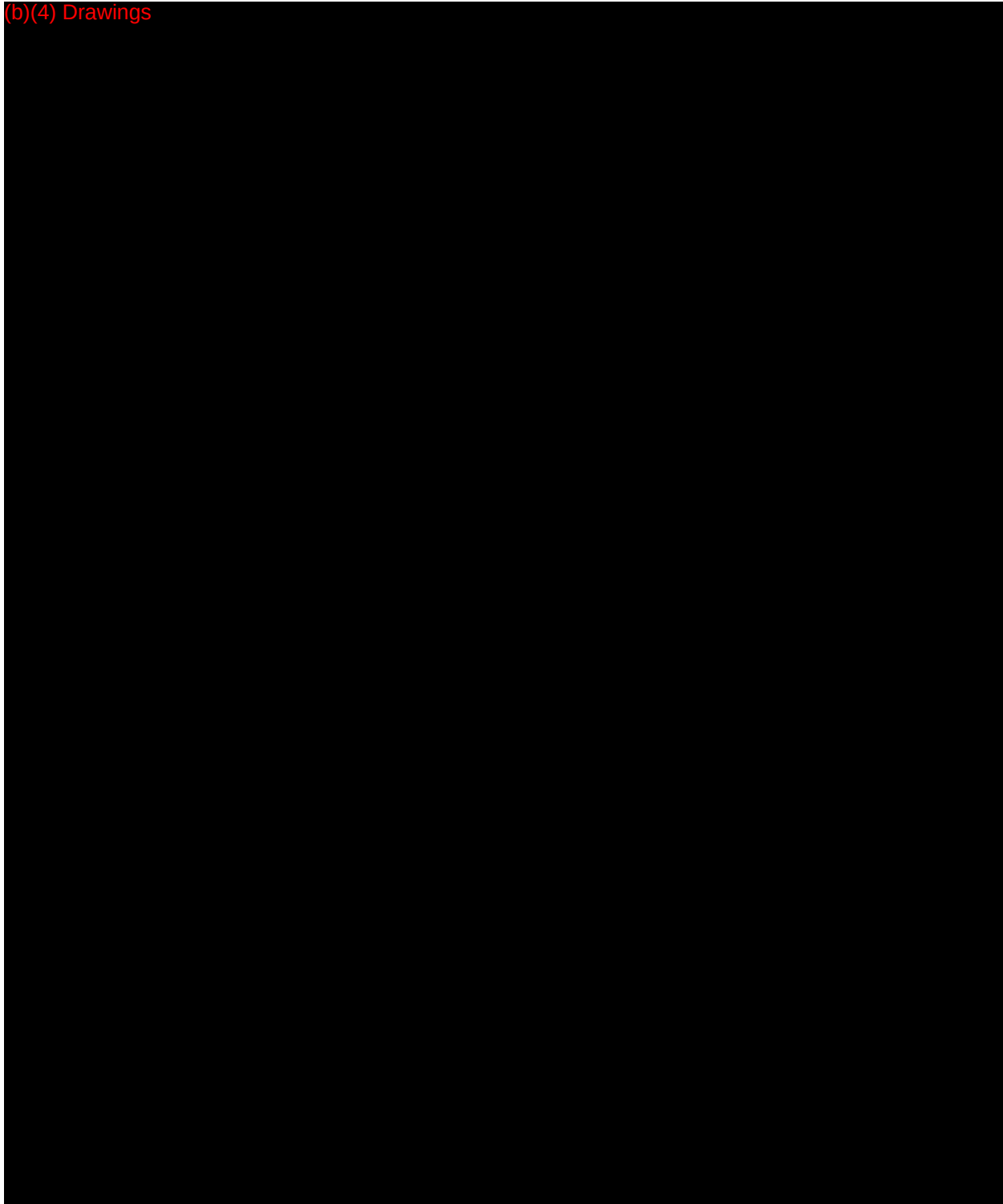


RFID Tag Examples:



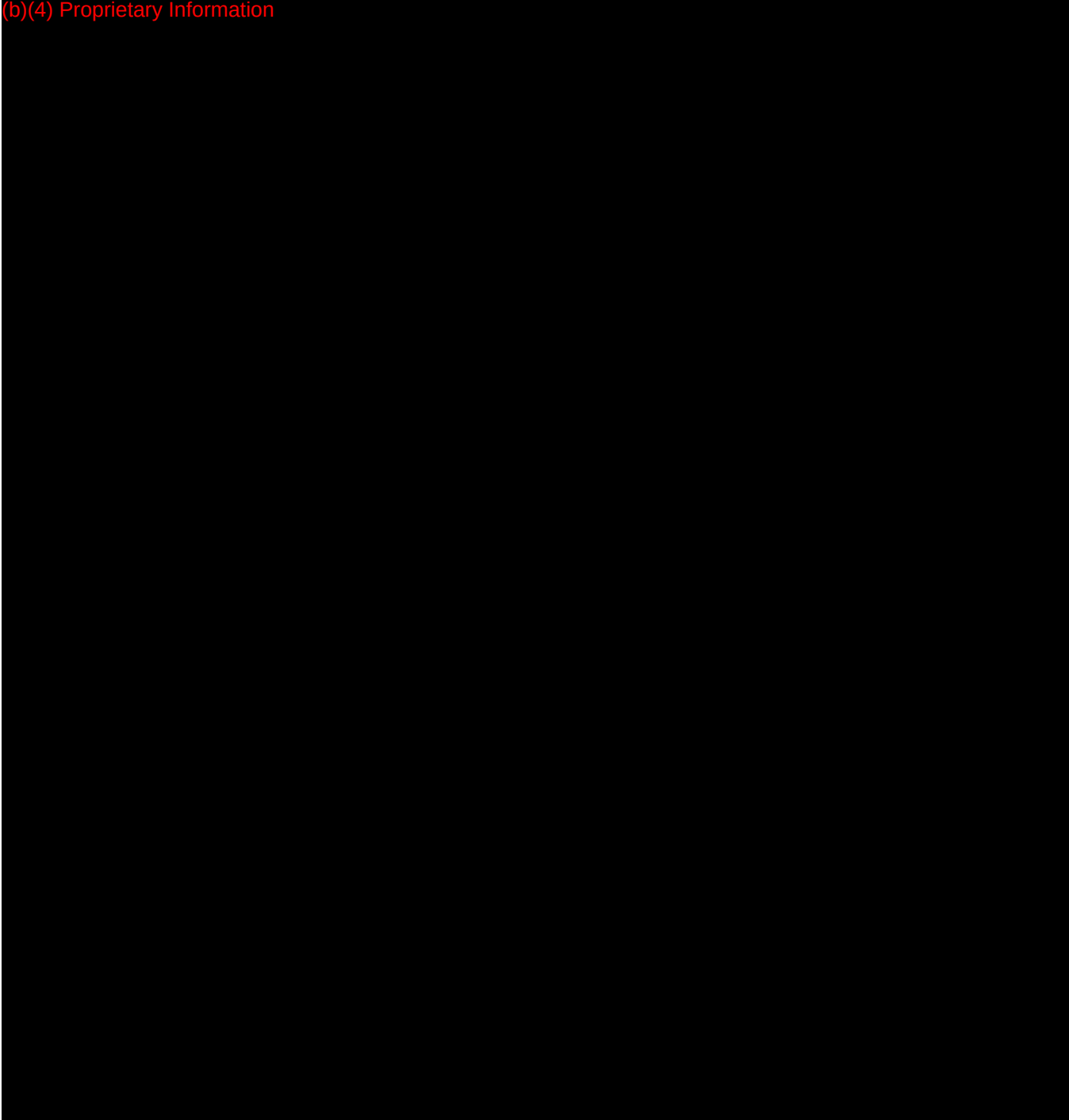
9 – DEVICE DESCRIPTION

(b)(4) Drawings



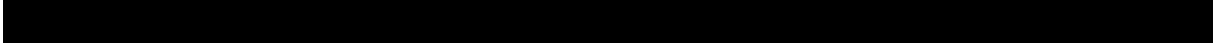
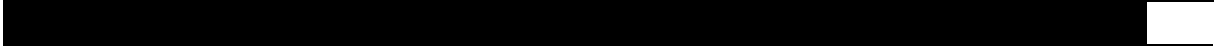
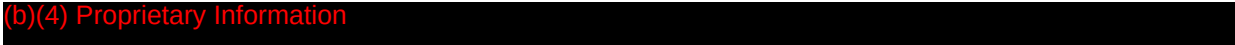
9 – DEVICE DESCRIPTION

(b)(4) Proprietary Information



Additional information

(b)(4) Proprietary Information



The composition and indications for use are identical. The only difference between the (b)(4) Proprietary and the subject device is the subject device is

Device Description – 9-4

9 – DEVICE DESCRIPTION

polished to a high gloss to differentiate. The polishing is performed by (b)(4) Proprietary information. Contractual controls are in place between the parties with respect to regulatory requirements, traceability and quality controls.

10 – SUBSTANTIAL EQUIVALENCE DISCUSSION**CONFIDENTIAL****Content**

Regulatory	1
Performance Data / Specification	1
Indications for use	2
Principles of operation	2
Device Description	3
Technology.....	3
Materials.....	4
Standards.....	4
Conclusion	4

Regulatory

Predicate device ZCAD (K132937)	Telio CAD Multi
FDA Classification Product Code: EBG	Same
FDA Regulation No. 872.3770	Same

Performance Data / Specification

Property	Standard	Value Predicate Device (K132937)	Value Subject Device
(b)(4) Proprietary Information			

10 – SUBSTANTIAL EQUIVALENCE DISCUSSION**CONFIDENTIAL****Discussion:**

The material is the same as the predicate device. (b)(4) Proprietary Information [REDACTED]. The only difference between the subject device and the predicate devices is that the subject device is polished on both sides to a glossy finish. This poses no difference in the substance, operating principles or biocompatibility of the device.

Indications for use

Predicate device (K132937)	Telio CAD Multi
510k clearance, Indications for Use Statement: <i>"The Harvest Dental Polymer Blocks (ZCAD) are PMMA blanks for manufacturing temporary crowns and bridges by a CAD/CAM system."</i>	• Provisional anterior and posterior crowns with a maximum wear period of up to 12 months. • Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months. • Provisional inlay and onlays

Discussion:

The changes in language between the predicate and the subject device only provide clarification as to the use of the device and do not pose a substantial difference.

Principles of operation

Predicate device (K132937)	Telio CAD Multi
The blocks are processed by dental technicians using CAD/CAM technology to create temporary restorations.	Same
Time in mouth: Long term temporary (more than 30 days, less than 12 months)	Same

Discussion:

The principles of operation are the same as the predicate.

10 – SUBSTANTIAL EQUIVALENCE DISCUSSION**CONFIDENTIAL****Device Description**

Predicate device (K132937)	Telio CAD Multi
PMMA in the form of polymerized Disc for the fabrication of long-term temporaries by means of the CAD/CAM technology.	PMMA in the form of polymerized discs for the fabrication of long-term temporaries by means of the CAD/CAM technology.
No accessories	No accessories
Product available in different thicknesses	Product available in four different thicknesses 12mm, 16mm, 20mm and 25mm
Available in one translucency: LT	Same
Available in various shades:	Same. Available in BL2, A1, A2, A3, A3.5, A4, B1, B2
Compatible with Wieland milling units or any other units accepting 98.5mm discs where open architecture CAM is used in the design, i.e. 3Shape	Same.
The disc delivered unpolished	The subject device is polished on both the top and bottom surfaces to a high gloss. This has no impact on the use, safety or effectiveness of the device.

Discussion:

See Drawing in Device Description Section 9. The device is the same as the predicate except for the polished surfaces.

Technology

Predicate device (K132937)	Telio CAD Multi
The processing steps for the fabrication of the desired restoration are described in the Instructions for Use.	Same
Connector dimensions: with 1 pontic: at least 12 mm ² with 2 pontics: at least 12 mm ²	Same
Polishing, finishing, lining,	Same
Seating/cementation: Intra-oral cementation using a eugenol-free temporary cement	Seating/cementation: Intra-oral cementation to tooth: Same
Storage conditions: no special conditions	Same
Shelf life: no special conditions	Same
Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.	Same

Discussion:

The technology to prepare temporary restorations is the same as for the predicate device.

10 – SUBSTANTIAL EQUIVALENCE DISCUSSION**CONFIDENTIAL****Materials**

Predicate device (K132937)	Telio CAD Multi
PMMA (CAS No. 6011-14-7) 99.898%	Same
Color pigments 0.1%	Same
Fluorescents <0.1%	Same

Discussion:

The material is the same as the predicate device. The biocompatibility studies for the predicate remain valid and no new biocompatibility testing is required.

Standards

Predicate device (K132937)	Telio CAD Multi
The device was tested to ISO 10477:2004 and ISO 20795-1 Dentistry – Base Polymers – Part 1: Denture base Polymers	The device was tested to ISO 10477:2004 and ISO 20795-1 Dentistry – Base Polymers – Part 1: Denture base Polymers

Discussion:

The new product and the predicate device have been tested with the same Standard.

Conclusion

The data show that TelioCAD Multi is substantially equivalent to the predicate device ZCAD (K132937).

11 – PROPOSED LABELING AND INSTRUCTIONS FOR USE

Included in this section of the submission are:

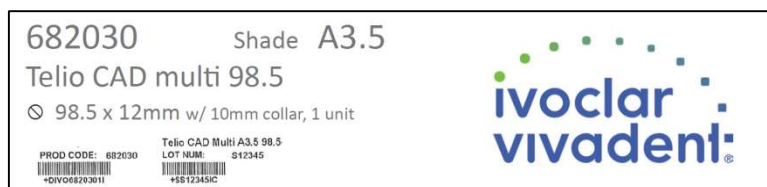
1. Box labeling
2. Instructions for Use.

Additional labeling appears on the device as follows:

1. Side labeling on device imprinted with Disc specific information, i.e. disc thickness, shade, lot, date of manufacture, expiration date and product code.

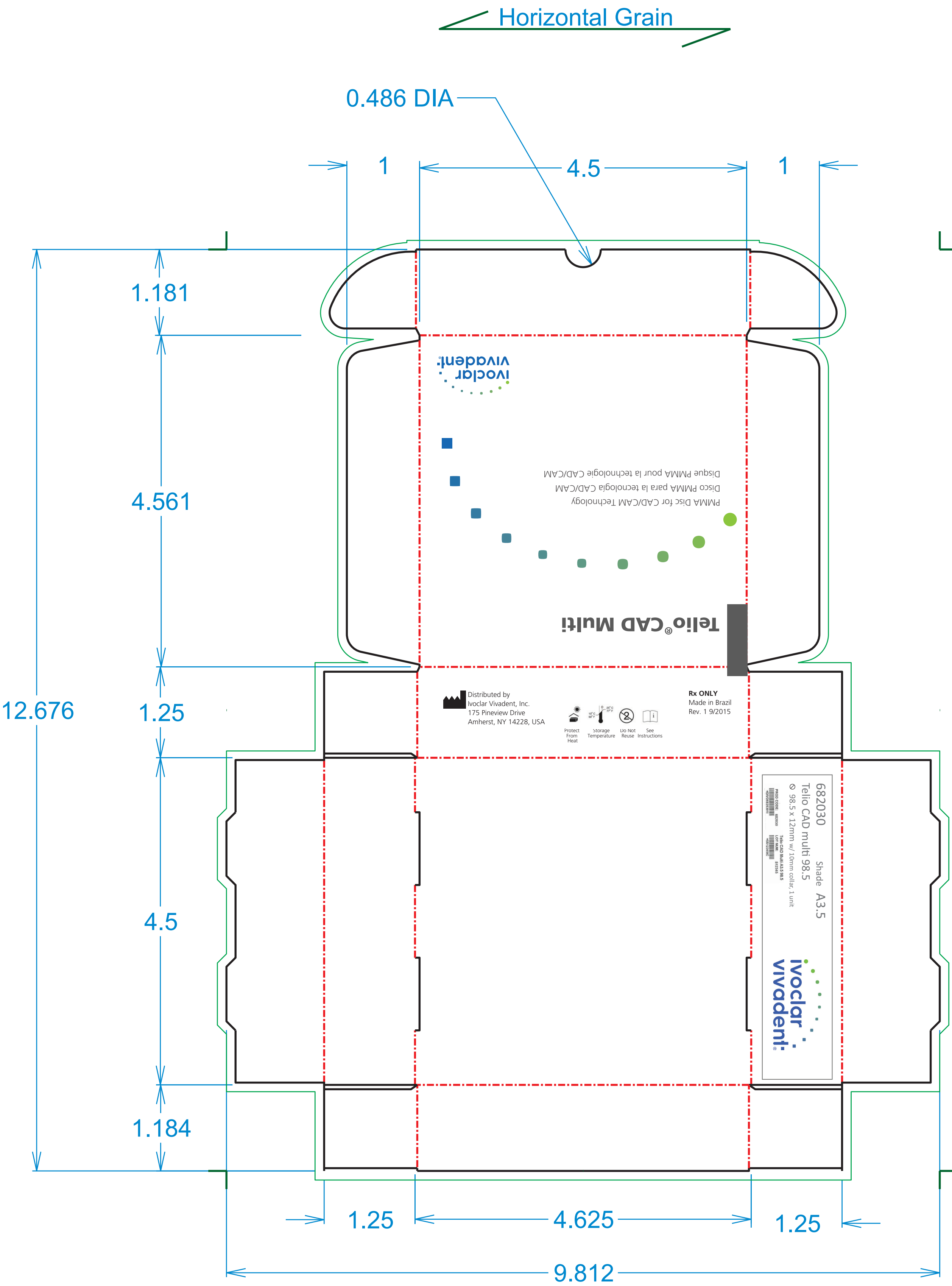


2. Barcode on box:



3. RFID Tag (Example only)– These tags are readable by the Wieland Select Milling unit for thickness.





Harvest Dental	Date: 09/22/2015
Item Description: ZCAD PMMA Disc box - Box 0-1.V1	
Size:	4+5/8 x 4+1/2 x 1+1/4
Stock:	.024 SBS
	Rev: 0



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PMMA Disc for CAD/CAM Technology
Disco PMMA para la tecnología CAD/CAM
Disque PMMA pour la technologie CAD/CAM

Instructions for Use
Mode d'emploi
Instrucciones de Uso

Telio® CAD Multi



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Rev 2. 12/2015



Questions? Contact FDA/CDRH/ODE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

INSTRUCTIONS FOR USE

Description

PMMA multiple layer disc for fabricating provisional restorations by a CAD/CAM system.

Indications

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays.

Contraindications

- Use for permanent restorations. Bridge designs involving more than two adjacent pontics.
- Patients suffering from parafunctions such as bruxism.
- In the case of known allergic reaction to any of its chemical constituents, restorations should not be made from Telio CAD.

Composition

- Polymethyl methacrylate (PMMA) and ester-based cross-linked polymers.
- Color pigments.

Shades

BL2, A1, A2, A3, A3.5, A4, B1, B2

Disc Sizes

12mm, 16mm, 20mm, 25mm

Hazard Warnings

Dust is created during the milling of Telio CAD Multi that can cause irritation of the eyes, skin and airways. Therefore always ensure that the extractor on your milling machine is functioning perfectly.

Storage

Protect the materials from direct sunlight. Observe the storage instructions and expiry date on the outer packaging. Keep out of reach of children.

Working Instructions

1. Mill PMMA discs while taking into account specific parameters for milling acrylic polymers.
2. Insert disc with arrow pointing up.
3. If using a Zenotec® select milling machine, the quality code (RFID label) enclosed with the product must be activated in the CAM system by means of the reader before milling.
4. Check milled framework for obvious chips or cracks, use only fault free framework for temporary restorations.
5. Ensure that milled framework is dust-free.
6. Use provisional, eugenol-free cements for installment inside the mouth.

Design

- For crowns, do not fall below the minimum wall thickness of 1mm.
- When designing bridges with one connected pontic, the connection cross-section between crown and pontic unit may not be less than 12 mm².
- When designing bridges with a range of up to two connected pontics, the connection cross-sections between crown and pontics may not be less than 12 mm².

Finishing

For trimming and separating frameworks, use a cross-cut tungsten carbide or separating disc suitable for acrylics.

Hints

Should intolerance to the product be suspected, use it only after an allergy screening test has been performed. Disinfect the milled parts before inserting them in the patient's mouth. These instructions for use are based on current levels of product knowledge. The user will be held fully responsible in regards to correct use of the product. The manufacturer is not liable for any unsatisfactory results, given that it has no control of processing procedures. The dental technician shall inform the dentist regarding the operations to be performed before inserting the part into the patient's mouth, making sure that the dentist has received all of the information contained in these instructions for use.

Mechanical Properties of PMMA Discs

Property	Value
Modulus of Elasticity	>2,200 MPa
Bending Strength	>100 MPa
Absorption of Water according to ISO 10477	<20µg /mm³
Water Solubility	<0.8µg /mm³

INSTRUCCIONES DE USO

Descripción

Disco de varias capas de PMMA para fabricar restauraciones provisionales mediante un sistema CAD/CAM.

Indicaciones

- Coronas provisionales anteriores y posteriores con un período de desgaste máximo de hasta 12 meses.
- Puentes provisionales anteriores y posteriores con hasta dos pñticos adyacentes con un período de desgaste máximo de hasta 12 meses.
- Incrustaciones y recubrimientos provisionales.

Contraindicaciones

- Uso para restauraciones permanentes. Diseños de puentes que abarquen más de dos pñticos adyacentes.
- Pacientes que padezcan parafunciones, como el bruxismo.
- Las restauraciones no deben elaborarse a partir de Telio CAD en caso de reacción alérgica conocida a cualquiera de sus componentes químicos.

Composición

- Polimetil metacrilato (PMMA) y polímeros reticulados basados en ésteres.
- Pigmentos de color.

Tonos

BL2, A1, A2, A3, A3.5, A4, B1 y B2

Tamaños del disco

12 mm, 16 mm, 20 mm y 25 mm

Advertencias de riesgo

Durante el triturado del Telio CAD Multi se crea polvo que puede provocar irritación de los ojos, la piel y las vías respiratorias. En consecuencia, asegúrese siempre de que el extractor de su equipo de triturado funciona perfectamente.

Almacenamiento

Proteja los materiales de la luz solar directa. Respete las instrucciones de conservación y la fecha de caducidad que figuran en el exterior del envase. Manténgase fuera del alcance de los niños.

Instrucciones de trabajo

1. Triture los discos de PMMA respetando los parámetros específicos de triturado de polímeros acrílicos.
2. Introduzca el disco con la flecha hacia arriba.
3. Si usa un equipo de triturado Zenotec® select debe activar en el sistema CAM el código de calidad (etiqueta RFID) que se adjunta con el producto, utilizando para ello el lector antes del triturado.
4. Revise para detectar la presencia de astillamientos o grietas en el marco de trituración; para las restauraciones temporales utilice solo marcos sin defectos.
5. Compruebe que no haya polvo en el marco de trituración.
6. Use cementos provisionales sin eugenol para la instalación en el interior de la boca.

Diseño

- Para las coronas, no prepare un grosor de la pared menor de 1 mm.
- Cuando diseñe puentes con un pñtico conectado, la sección transversal de la conexión entre la corona y la unidad del pñtico no puede ser menor de 12 mm².
- Cuando diseñe puentes con una serie de hasta dos pñticos conectados, las secciones transversales de la conexión entre la corona y los pñticos no pueden ser menores de 12 mm².

Acabado

Para recortar y separar los marcos, use un disco de carburo de tungsteno para corte o para separación idóneo para material acrílico.

Sugerencias

Si se sospecha intolerancia al producto, úselo solo después de realizar una prueba de detección de alergias. Desinfecte las partes trituradas antes de insertarlas en la boca del paciente. Estas instrucciones de uso se basan en los niveles actuales de conocimiento del producto. El usuario tendrá toda la responsabilidad en lo que respecta al uso correcto del producto. El fabricante no es responsable de ningún resultado no satisfactorio, dado que no tiene control de los procedimientos de procesado. El técnico odontólogo informará al dentista de las operaciones que deben realizarse antes de insertar el componente en la boca del paciente, y se asegurará de que el dentista haya recibido toda la información contenida en estas instrucciones de uso.

Propiedades mecánicas de los discos de PMMA

Propiedad	Valor
Módulo de elasticidad	> 2200 MPa
Fuerza de doblamiento	> 100 MPa
Absorción de agua conforme a la norma ISO 10477	< 20 µg/mm³
Solubilidad en agua	< 0,8 µg/mm³

MODE D'EMPLOI

Description

Disque PMMA à plusieurs couches pour fabrication de restaurations provisoires à l'aide d'un système CAD/CAM.

Indications

- Couronnes antérieures et postérieures provisoires pour une durée maximale en bouche de 12 mois.
- Bridges antérieurs et postérieurs provisoires avec deux éléments intermédiaires adjacents maximum pour une durée maximale en bouche de 12 mois.
- Inlays et onlays provisoires.

Contre-indications

- Utilisation pour restaurations permanentes. Réalisation de bridges avec plus de deux éléments intermédiaires adjacents.
- Patients présentant des parafonctions, par exemple bruxisme.
- En cas de réaction allergique connue à l'un de ses constituants chimiques, les restaurations ne doivent pas être faites à partir de Telio CAD

Composants

- Méthacrylate de polyméthyle (PPMA) et polymères réticulés à base d'ester.
- Pigments de couleur.

Teintes

BL2, A1, A2, A3, A3.5, A4, B1, B2

Tailles des disques

12mm, 16mm, 20mm, 25mm

Mises en garde

De la poussière est créée pendant l'usinage de Telio CAD Multi qui peut causer l'irritation des yeux, de la peau et des voies aériennes. Par conséquent, toujours veiller à ce que l'extracteur de la machine d'usinage fonctionne parfaitement.

Stockage

Protéger les matériaux de la lumière directe du soleil. Respecter les consignes de conservation et la date de péremption indiquées sur l'emballage extérieur. Garder hors de portée des enfants.

Instructions de travail

1. Usiner les disques PMMA en tenant compte des paramètres spécifiques d'usinage des polymères acryliques.
2. Insérer le disque avec la flèche orientée vers le haut.
3. En cas d'utilisation d'une machine d'usinage Zenotec® select, le code de qualité (étiquette IRF) joint au produit doit être activé dans le système CAM au moyen du lecteur avant l'usinage.
4. Vérifier le cadre usiné pour détecter les ébrèchures ou les fissures évidentes, utiliser seulement un cadre sans défaut pour les restaurations provisoires.
5. Veiller à ce que le cadre usiné ne comporte pas de poussière.
6. Utiliser du ciment temporaire sans eugénol pour l'installation en bouche.

Conception

- Pour les couronnes, maintenir une paroi d'une épaisseur minimale de 1 mm.
- Lorsque vous concevez des bridges avec un élément intermédiaire connecté, la section transversale de connexion entre la couronne et l'élément intermédiaire ne doit pas être inférieure à 12 mm².
- Lorsque vous concevez des bridges avec jusqu'à deux éléments intermédiaires connectés, les sections transversales de connexion entre la couronne et les éléments intermédiaires ne doivent pas être inférieures à 12 mm².

Finition

Pour la finition et pour séparer les cadres, utiliser des fraises en carbure de tungstène à denture croisée ou un disque de séparation adapté à l'acrylique.

Conseils

Si l'on soupçonne une intolérance au produit, il doit être utilisé seulement après avoir effectué un test de dépistage d'allergies. Désinfecter les portions usinées avant de les insérer dans la bouche du patient. Ces instructions d'utilisation sont basées sur les niveaux actuels de connaissance du produit. La responsabilité de l'utilisateur quant à l'utilisation correcte du produit sera totale. Le fabricant n'est pas responsable de tout résultat insatisfaisant, étant donné qu'il n'a aucun contrôle sur les procédures de traitement. Le technicien dentaire informera le dentiste concernant les opérations devant être effectuées avant d'insérer le produit dans la bouche du patient et devra s'assurer que le dentiste a reçu toutes les informations contenues dans ce mode d'emploi.

Propriétés mécaniques des disques PMMA

Propriété	Valeur
Module d'élasticité	> 2 200 MPa
Résistance à la flexion	> 100 MPa
Absorption d'eau selon l'ISO 10477	< 20 µg /mm³
Hydrosolubilité	< 0,8 µg /mm³

The subject device is intended to be marketed in a non-sterile state and sterilization is not recommended by the user. This is customary for these types of dental devices.

The device will include a 10 year shelf life. Included in this section of the submission is the Long Term Shelf-Life Testing Table provided by the Contract Manufacturer which supports a 10 year shelf life.

13 – BIOCOMPATIBILITY

The subject device is identical to the predicate device by way of composition, packaging and indications for use. There are no new issues relating to the subject device which warrants a new assessment of the Biocompatibility.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number (if known)
K153753

Device Name
TelioCAD Multi

Indications for Use (Describe)

For manufacturing by a CAD/CAM System:

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months
- Provisional inlay and onlays

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Disco PMMA para la tecnología CAD/CAM
Disque PMMA pour la technologie CAD/CAM

Instructions for Use
Mode d'emploi
Instrucciones de Uso

Telio® CAD Multi!



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Rev 1. 3/2016



INSTRUCTIONS FOR USE

Description

PMMA multiple layer disc for fabricating provisional restorations by a CAD/CAM system.

Indications: For manufacturing by a CAD/CAM System:

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays.

Contraindications

- Use for permanent restorations. Bridge designs involving more than two adjacent pontics.
- Patients suffering from parafunctions such as bruxism.
- In the case of known allergic reaction to any of its chemical constituents, restorations should not be made from Telio CAD.

Composition

- Polymethyl methacrylate (PMMA) and ester-based cross-linked polymers.
- Color pigments.

Shades

BL2, A1, A2, A3, A3.5, A4, B1, B2

Disc Sizes

12mm, 16mm, 20mm, 25mm

Hazard Warnings

Dust is created during the milling of Telio CAD Multi that can cause irritation of the eyes, skin and airways. Therefore always ensure that the extractor on your milling machine is functioning perfectly.

Storage

Protect the materials from direct sunlight. Observe the storage instructions and expiry date on the outer packaging. Keep out of reach of children.

Working Instructions

1. Mill PMMA discs while taking into account specific parameters for milling acrylic polymers.
2. Insert disc with arrow pointing up.
3. If using a Zenotec® select milling machine, the quality code (RFID label) enclosed with the product must be activated in the CAM system by means of the reader before milling.
4. Check milled framework for obvious chips or cracks, use only fault free framework for temporary restorations.
5. Ensure that milled framework is dust-free.
6. Use provisional, eugenol-free cements for installment inside the mouth.

Design

- For crowns, do not fall below the minimum wall thickness of 1mm.
- When designing bridges with one connected pontic, the connection cross-section between crown and pontic unit may not be less than 12 mm².
- When designing bridges with a range of up to two connected pontics, the connection cross-sections between crown and pontics may not be less than 12 mm².

Finishing

For trimming and separating frameworks, use a cross-cut tungsten carbide or separating disc suitable for acrylics.

Hints

Should intolerance to the product be suspected, use it only after an allergy screening test has been performed. Disinfect the milled parts before inserting them in the patient's mouth. These instructions for use are based on current levels of product knowledge. The user will be held fully responsible in regards to correct use of the product. The manufacturer is not liable for any unsatisfactory results, given that it has no control of processing procedures. The dental technician shall inform the dentist regarding the operations to be performed before inserting the part into the patient's mouth, making sure that the dentist has received all of the information contained in these instructions for use.

Mechanical Properties of PMMA Discs

Property	Value
Modulus of Elasticity	>2,200 MPa
Flexural Strength	>100 MPa
Toughness	>100 KJ/m²(Izod)>1.3KJ/m²
Bond Strength	>7 MPa
Vickers Hardness	HV (0.05/10) >135
Water Sorption	<20µg /mm³
Water Solubility	<0.8µg /mm³
Residual Monomer Content	(24h at 37°C and 30 min in air) <0.7%
Burning Residual	(2h 500°C) (Clear)

510(K) SUMMARY



TelioCAD Multi
Rev March 4, 2016

Contact: Donna Marie Hartnett

Company: Ivoclar Vivadent, Inc.
175 Pineview Drive, Amherst, NY 14228
+716-691-0010

Date Prepared: March 4, 2016

Proprietary Name: **Telio® CAD Multi**

Classification Name: Crown and Bridge, Temporary, Resin (872.3770)
(Classification Code EBG)

Device Description: Telio CAD Multi are PMMA discs used for fabrication of long-term temporaries by means of CAD/CAM technology. The PMMA discs have a Long-term (12-month) wear period and durable shade stability with lifelike layered appearance. The device is available in 8 shades (BL2, A1, A2, A3, A3.5, A4, B1 and B2) and 4 thicknesses 12mm, 16mm, 20mm and 25mm. They are the standard 98.5 mm in diameter to permit use with the Wieland Select Milling equipment or other equipment which accepts 98.5 mm discs. The material exhibits high homogeneity due to industrial manufacturing process and temporaries can be easily reproduced using the CAD/CAM Technology. The device is contraindicated for use in permanent restorations and bridge designs involving more than two adjacent pontics. The device should not be used in patients with para-functional habits, ex. Bruxism or patients known to be allergic to the ingredients.

Indications for Use:

For manufacturing by a CAD/CAM system:

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays

Predicate Device: ZCAD Temp Esthetic (K132937) by Harvest Dental (Brea,CA)

Secondary predicates for reference:

1. Idodontine (Dental Polymer Blank) (K150432) to support 12 month long term wear claim
2. Vipi Block (K102341) for composition and biocompatibility.

510(K) SUMMARY

TelioCAD Multi
Rev March 4, 2016



Comparison to predicate device: The predicate device to which Telio CAD Multi has been compared is ZCAD Temp Esthetic (K132937). For this application, Telio CAD Multi has been compared to its predicate with regard to chemical composition, performance data, principles of operation and Instructions for Use and indications for use. Additional secondary predicates have been referenced as stated above to support long term wear claim of up to 12 months and to provide additional comparison with respect to composition and biocompatibility. The comparison shows that Telio CAD Multi is substantially equivalent to the predicate device.

Testing Summary: The subject device was not tested for Biocompatibility as no new elements are used in the chemical composition as compared to the predicate device. Biocompatibility evaluation was carried out according to ISO 10993-1 and ISO 7504. No changes have been made which will affect biocompatibility. The device was tested according to ISO 10477:2004 Dentistry – Polymer based crown and bridge materials for Surface finish, Flexural Strength, Bond strength, Water Sorption, Solubility, Shade Consistency and Color stability and the device met all requirements of the standard. The device was also tested according to ISO 20795-1:2013 Dentistry – Base Polymers – Part 1: Denture Base Polymers for Modulus of Elasticity and Residual monomer and the device met these requirements. Finally, testing according to ISO 179-1:2010 for Charpy toughness, ISO 180:2000 for izod impact strength and ISO 868:2003 for Vickers Hardness (converted from Shore D), was conducted to provide additional insight as to the properties of the materials for its intended use.

Conclusion: The above data and analysis demonstrates that Telio®CAD Multi is substantially equivalent to the predicate device.

9 – DEVICE DESCRIPTION

Revised March 4, 2016

Telio CAD Multi consists of polymer (PMMA) blocks for the fabrication of long-term temporaries using CAD/CAM technology. The discs include fluorescent particles to give the appearance of multi layering for a more favorable esthetic result in the final restoration. Telio CAD Multi restorations are either milled in the dental practice utilizing a chairside design/milling system or in the dental laboratory. The restorations can be polished quickly and efficiently before insertion.

INDICATIONS FOR USE

For manufacturing by a CAD/CAM system:

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays

The PMMA discs have a Long-term (12-month) wear period and durable shade stability with lifelike layered appearance. The device is available in 8 shades (BL2, A1, A2, A3, A3.5, A4, B1 and B2) and 4 thicknesses 12mm, 16mm, 20mm and 25mm. They are the standard 98.5 mm in diameter to permit use with the Wieland Select Milling equipment or other equipment which accepts 98.5 mm discs. The material exhibits high homogeneity due to industrial manufacturing process and temporaries can be easily reproduced using the CAD/CAM Technology.

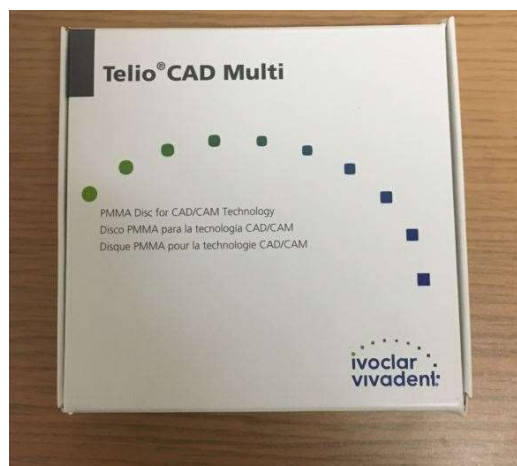
The device is contraindicated for use in permanent restorations and bridge designs involving more than two adjacent pontics. The device should not be used in patients with para-functional habits, ex. Bruxism or patients known to be allergic to the ingredients.

The discs are sold as single units, packaged in a cardboard box with protective foam. They are labeled with an RFID label in order for the milling machine (equipment with a reader) to identify thickness and shade. The RFID label includes the relevant identification information, diameter, height and shade, as well as an “UP” arrow for proper insertion into the milling unit.

9 – DEVICE DESCRIPTION

Revised March 4, 2016

Top View Box:



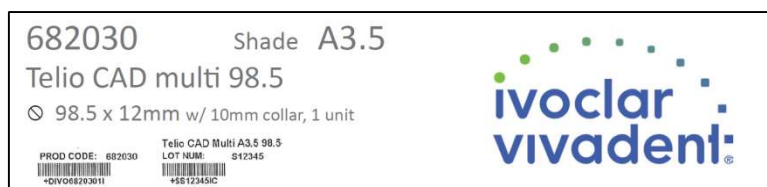
Full Box Detail:



Side labeling on disc



Barcode on side of box



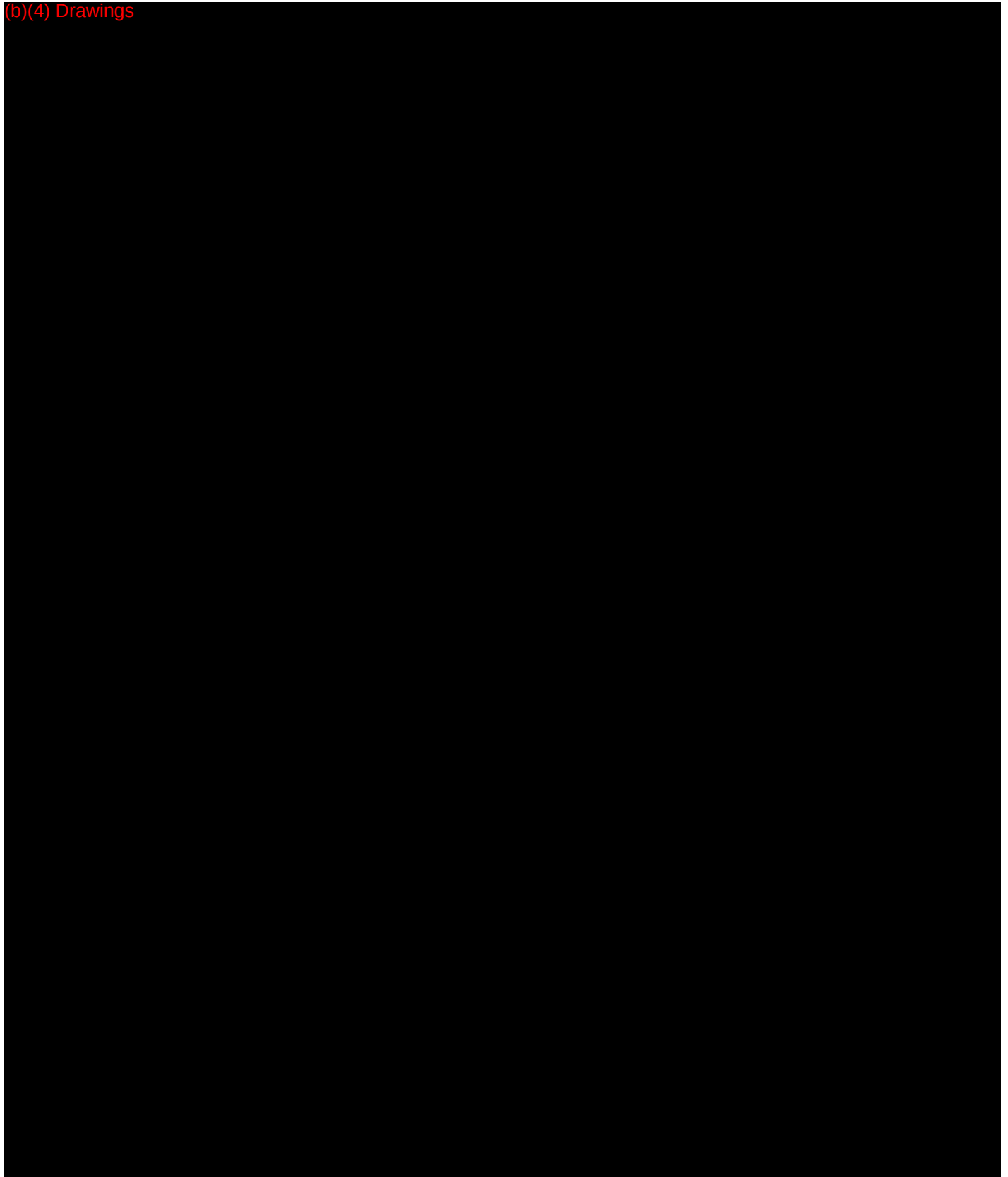
RFID Tag Examples:



9 – DEVICE DESCRIPTION

Revised March 4, 2016

(b)(4) Drawings



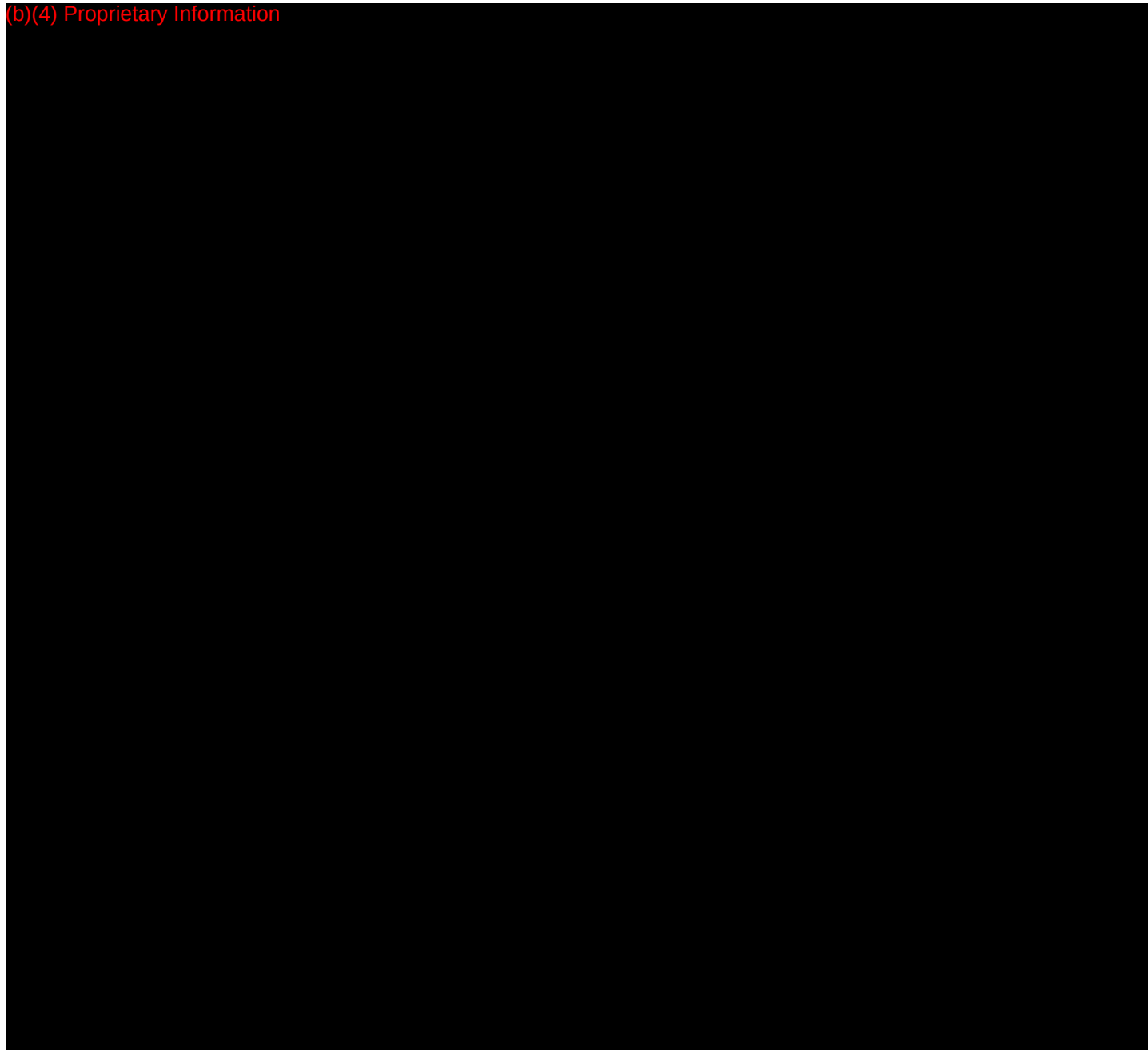
9 – DEVICE DESCRIPTION

Revised March 4, 2016

The discs are compatible with the Wieland Select milling equipment and any other machines where a 95.5mm disc can be milled.

COMPOSITION

(b)(4) Proprietary Information



9 – DEVICE DESCRIPTION

Revised March 4, 2016

Additional information

(b)(4) Proprietary Information

k. The composition and indications for use are identical. The only difference between the (b)(4) Proprietary and the subject device is the subject device is polished to a high gloss to differentiate. The polishing is performed by (b)(4) Proprietary Information. Contractual controls are in place between the parties with respect to regulatory requirements, traceability and quality controls.

(b)(4)

(b)(4)

TEST REPORT

(b)(4)

Date: 11/25/2015



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

April 12, 2016

Ivoclar Vivadent, Inc.
Ms. Donna Marie Hartnett, Esq.
Director QA/Regulatory Affairs
175 Pineview Drive
Amherst, New York 14228

Re: K153753

Trade/Device Name: TelioCAD Multi
Regulation Number: 21 CFR 872.3770
Regulatory Class: Class II
Product Code: EBG
Dated: March 4, 2016
Received: March 8, 2016

Dear Ms. Donna Marie Hartnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Page 2 – Ms. Donna Marie Hartnett

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and

Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 12, 2016

Ivoclar Vivadent, Inc.
Ms. Donna Marie Hartnett, Esq.
Director QA/Regulatory Affairs
175 Pineview Drive
Amherst, New York 14228

Re: K153753

Trade/Device Name: TelioCAD Multi
Regulation Number: 21 CFR 872.3770
Regulatory Class: Class II
Product Code: EBG
Dated: March 4, 2016
Received: March 8, 2016

Dear Ms. Donna Marie Hartnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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Page 2 – Ms. Donna Marie Hartnett

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<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and

Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number (if known)
K153753

Device Name
TelioCAD Multi

Indications for Use (Describe)

For manufacturing by a CAD/CAM System:

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months
- Provisional inlay and onlays

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

TelioCAD Multi
Rev April 11, 2016



Contact: Donna Marie Hartnett

Company: Ivoclar Vivadent, Inc.
175 Pineview Drive, Amherst, NY 14228
+716-691-0010

Date Prepared: April 11, 2016

Proprietary Name: **Telio® CAD Multi**

Classification Name: Crown and Bridge, Temporary, Resin (872.3770)
(Classification Code EBG)

Device Description: Telio CAD Multi are PMMA discs used for fabrication of long-term temporaries by means of CAD/CAM technology. The PMMA discs have a Long-term (12-month) wear period and durable shade stability with lifelike layered appearance. The device is available in 8 shades (BL2, A1, A2, A3, A3.5, A4, B1 and B2) and 4 thicknesses 12mm, 16mm, 20mm and 25mm. They are the standard 98.5 mm in diameter to permit use with the Wieland Select Milling equipment or other equipment which accepts 98.5 mm discs. The material exhibits high homogeneity due to industrial manufacturing process and temporaries can be easily reproduced using the CAD/CAM Technology. The device is contraindicated for use in permanent restorations and bridge designs involving more than two adjacent pontics. The device should not be used in patients with para-functional habits, ex. Bruxism or patients known to be allergic to the ingredients.

Indications for Use:

For manufacturing by a CAD/CAM system:

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays

Predicate Device: ZCAD Temp Esthetic (K132937) by Harvest Dental (Brea,CA)

Secondary predicates for reference:

1. Idodentine (Dental Polymer Blank) (K150432) to support 12 month long term wear claim
2. Vipi Block (K102341) for composition and biocompatibility.

510(K) SUMMARY

TelioCAD Multi
Rev April 11, 2016

**Indications for use**

Predicate device (K132937)	Telio CAD Multi
510k clearance, Indications for Use Statement: <i>"The Harvest Dental Polymer Blocks (ZCAD) are PMMA blanks for manufacturing temporary crowns and bridges by a CAD/CAM system."</i>	• Provisional anterior and posterior crowns with a maximum wear period of up to 12 months. • Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months. • Provisional inlay and onlays
Predicate device (K150432)	Telio CAD Multi
Time in mouth: Long term temporary (more than 30 days, less than 12 months)	Time in mouth: Long term temporary (more than 30 days, less than 12 months)

Principles of operation

Predicate device (K132937)	Telio CAD Multi
The blocks are processed by dental technicians using CAD/CAM technology to create temporary restorations.	The blocks are processed by dental technicians using CAD/CAM technology to create temporary restorations.

Device Description

Predicate device (K132937)	Telio CAD Multi
PMMA in the form of polymerized Disc for the fabrication of long-term temporaries by means of the CAD/CAM technology.	PMMA in the form of polymerized discs for the fabrication of long-term temporaries by means of the CAD/CAM technology.
No accessories	No accessories
Product available in different thicknesses	Product available in four different thicknesses 12mm, 16mm, 20mm and 25mm
Available in one translucency: LT	Available in one translucency: LT
Available in various shades:	Available in BL2, A1, A2, A3, A3.5, A4, B1, B2
Compatible with Wieland milling units or any other units accepting 98.5mm discs where open architecture CAM is used in the design, i.e. 3Shape	Compatible with Wieland milling units or any other units accepting 98.5mm discs where open architecture CAM is used in the design, i.e. 3Shape
The disc delivered unpolished	The subject device is polished on both the top and bottom surfaces to a high gloss. This has no impact on the use, safety or effectiveness of the device.

510(K) SUMMARY

TelioCAD Multi
Rev April 11, 2016

**Technology**

Predicate device (K132937)	Telio CAD Multi
The processing steps for the fabrication of the desired restoration are described in the Instructions for Use.	The processing steps for the fabrication of the desired restoration are described in the Instructions for Use.
Connector dimensions: with 1 pontic: at least 12 mm ² with 2 pontics: at least 12 mm ²	Connector dimensions: with 1 pontic: at least 12 mm ² with 2 pontics: at least 12 mm ²
Polishing, finishing, lining,	Polishing, finishing, lining,
Seating/cementation: Intra-oral cementation using a eugenol-free temporary cement	Seating/cementation: Intra-oral cementation to tooth using a eugenol-free temporary cement
Storage conditions: no special conditions	Storage conditions: no special conditions
Shelf life: no special conditions	Shelf life: no special conditions
Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.	Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.

Materials

Predicate device (K132937)	Telio CAD Multi
PMMA	PMMA

Standards

Predicate device (K132937)	Telio CAD Multi
The device was tested to ISO 10477:2004 and ISO 20795-1 Dentistry – Base Polymers – Part 1: Denture base Polymers	The device was tested to ISO 10477:2004 and ISO 20795-1 Dentistry – Base Polymers – Part 1: Denture base Polymers

Testing Summary: The subject device was not tested for Biocompatibility as no new elements are used in the chemical composition as compared to the predicate device. Biocompatibility evaluation was carried out according to ISO 10993-1 and ISO 7504. No changes have been made which will affect biocompatibility. The device was tested according to ISO 10477:2004 Dentistry – Polymer based crown and bridge materials for Surface finish, Flexural Strength, Bond strength, Water Sorption, Solubility, Shade Consistency and Color stability and the device met all requirements of the standard. The devices was also tested according to ISO 20795-1 :2013 Dentistry – Base Polymers – Part 1: Denture Base Polymers for5 Modulus of Elasticity and Residual monomer and the device met these requirements. Finally, testing according to ISO 179-1:2010 for Charpy toughness, ISO 180:2000 for izod impact strength and ISO 868:2003 for Vickers Hardness (converted from Shore D), was conducted to provide additional insight as to the properties of the materials for its intended use.

Conclusion: The above data and analysis demonstrates that Telio@CAD Multi is substantially equivalent to the predicate device.

510(K) SUMMARY

TelioCAD Multi
Rev April 11, 2016



Contact: Donna Marie Hartnett

Company: Ivoclar Vivadent, Inc.
175 Pineview Drive, Amherst, NY 14228
+716-691-0010

Date Prepared: April 11, 2016

Proprietary Name: **Telio® CAD Multi**

Classification Name: Crown and Bridge, Temporary, Resin (872.3770)
(Classification Code EBG)

Device Description: Telio CAD Multi are PMMA discs used for fabrication of long-term temporaries by means of CAD/CAM technology. The PMMA discs have a Long-term (12-month) wear period and durable shade stability with lifelike layered appearance. The device is available in 8 shades (BL2, A1, A2, A3, A3.5, A4, B1 and B2) and 4 thicknesses 12mm, 16mm, 20mm and 25mm. They are the standard 98.5 mm in diameter to permit use with the Wieland Select Milling equipment or other equipment which accepts 98.5 mm discs. The material exhibits high homogeneity due to industrial manufacturing process and temporaries can be easily reproduced using the CAD/CAM Technology. The device is contraindicated for use in permanent restorations and bridge designs involving more than two adjacent pontics. The device should not be used in patients with para-functional habits, ex. Bruxism or patients known to be allergic to the ingredients.

Indications for Use:

For manufacturing by a CAD/CAM system:

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays

Predicate Device: ZCAD Temp Esthetic (K132937) by Harvest Dental (Brea,CA)

Secondary predicates for reference:

1. Idodentine (Dental Polymer Blank) (K150432) to support 12 month long term wear claim
2. Vipi Block (K102341) for composition and biocompatibility.

510(K) SUMMARY

TelioCAD Multi
Rev April 11, 2016

**Indications for use**

Predicate device (K132937)	Telio CAD Multi
510k clearance, Indications for Use Statement: <i>"The Harvest Dental Polymer Blocks (ZCAD) are PMMA blanks for manufacturing temporary crowns and bridges by a CAD/CAM system."</i>	• Provisional anterior and posterior crowns with a maximum wear period of up to 12 months. • Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months. • Provisional inlay and onlays
Predicate device (K150432)	Telio CAD Multi
Time in mouth: Long term temporary (more than 30 days, less than 12 months)	Time in mouth: Long term temporary (more than 30 days, less than 12 months)

Principles of operation

Predicate device (K132937)	Telio CAD Multi
The blocks are processed by dental technicians using CAD/CAM technology to create temporary restorations.	The blocks are processed by dental technicians using CAD/CAM technology to create temporary restorations.

Device Description

Predicate device (K132937)	Telio CAD Multi
PMMA in the form of polymerized Disc for the fabrication of long-term temporaries by means of the CAD/CAM technology.	PMMA in the form of polymerized discs for the fabrication of long-term temporaries by means of the CAD/CAM technology.
No accessories	No accessories
Product available in different thicknesses	Product available in four different thicknesses 12mm, 16mm, 20mm and 25mm
Available in one translucency: LT	Available in one translucency: LT
Available in various shades:	Available in BL2, A1, A2, A3, A3.5, A4, B1, B2
Compatible with Wieland milling units or any other units accepting 98.5mm discs where open architecture CAM is used in the design, i.e. 3Shape	Compatible with Wieland milling units or any other units accepting 98.5mm discs where open architecture CAM is used in the design, i.e. 3Shape
The disc delivered unpolished	The subject device is polished on both the top and bottom surfaces to a high gloss. This has no impact on the use, safety or effectiveness of the device.

510(K) SUMMARY

TelioCAD Multi
Rev April 11, 2016

**Technology**

Predicate device (K132937)	Telio CAD Multi
The processing steps for the fabrication of the desired restoration are described in the Instructions for Use.	The processing steps for the fabrication of the desired restoration are described in the Instructions for Use.
Connector dimensions: with 1 pontic: at least 12 mm ² with 2 pontics: at least 12 mm ²	Connector dimensions: with 1 pontic: at least 12 mm ² with 2 pontics: at least 12 mm ²
Polishing, finishing, lining,	Polishing, finishing, lining,
Seating/cementation: Intra-oral cementation using a eugenol-free temporary cement	Seating/cementation: Intra-oral cementation to tooth using a eugenol-free temporary cement
Storage conditions: no special conditions	Storage conditions: no special conditions
Shelf life: no special conditions	Shelf life: no special conditions
Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.	Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.

Materials

Predicate device (K132937)	Telio CAD Multi
PMMA	PMMA

Standards

Predicate device (K132937)	Telio CAD Multi
The device was tested to ISO 10477:2004 and ISO 20795-1 Dentistry – Base Polymers – Part 1: Denture base Polymers	The device was tested to ISO 10477:2004 and ISO 20795-1 Dentistry – Base Polymers – Part 1: Denture base Polymers

Testing Summary: The subject device was not tested for Biocompatibility as no new elements are used in the chemical composition as compared to the predicate device. Biocompatibility evaluation was carried out according to ISO 10993-1 and ISO 7504. No changes have been made which will affect biocompatibility. The device was tested according to ISO 10477:2004 Dentistry – Polymer based crown and bridge materials for Surface finish, Flexural Strength, Bond strength, Water Sorption, Solubility, Shade Consistency and Color stability and the device met all requirements of the standard. The devices was also tested according to ISO 20795-1 :2013 Dentistry – Base Polymers – Part 1: Denture Base Polymers for5 Modulus of Elasticity and Residual monomer and the device met these requirements. Finally, testing according to ISO 179-1:2010 for Charpy toughness, ISO 180:2000 for izod impact strength and ISO 868:2003 for Vickers Hardness (converted from Shore D), was conducted to provide additional insight as to the properties of the materials for its intended use.

Conclusion: The above data and analysis demonstrates that Telio@CAD Multi is substantially equivalent to the predicate device.

510(K) SUMMARY

TelioCAD Multi
Rev April 11, 2016



Contact: Donna Marie Hartnett

Company: Ivoclar Vivadent, Inc.
175 Pineview Drive, Amherst, NY 14228
+716-691-0010

Date Prepared: April 11, 2016

Proprietary Name: **Telio® CAD Multi**

Classification Name: Crown and Bridge, Temporary, Resin (872.3770)
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Indications for Use:

For manufacturing by a CAD/CAM system:

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays

Predicate Device: ZCAD Temp Esthetic (K132937) by Harvest Dental (Brea,CA)

Secondary predicates for reference:

1. Idodentine (Dental Polymer Blank) (K150432) to support 12 month long term wear claim
2. Vipi Block (K102341) for composition and biocompatibility.

510(K) SUMMARY

TelioCAD Multi
Rev April 11, 2016

**Indications for use**

Predicate device (K132937)	Telio CAD Multi
510k clearance, Indications for Use Statement: <i>"The Harvest Dental Polymer Blocks (ZCAD) are PMMA blanks for manufacturing temporary crowns and bridges by a CAD/CAM system."</i>	• Provisional anterior and posterior crowns with a maximum wear period of up to 12 months. • Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months. • Provisional inlay and onlays
Predicate device (K150432)	Telio CAD Multi
Time in mouth: Long term temporary (more than 30 days, less than 12 months)	Time in mouth: Long term temporary (more than 30 days, less than 12 months)

Principles of operation

Predicate device (K132937)	Telio CAD Multi
The blocks are processed by dental technicians using CAD/CAM technology to create temporary restorations.	The blocks are processed by dental technicians using CAD/CAM technology to create temporary restorations.

Device Description

Predicate device (K132937)	Telio CAD Multi
PMMA in the form of polymerized Disc for the fabrication of long-term temporaries by means of the CAD/CAM technology.	PMMA in the form of polymerized discs for the fabrication of long-term temporaries by means of the CAD/CAM technology.
No accessories	No accessories
Product available in different thicknesses	Product available in four different thicknesses 12mm, 16mm, 20mm and 25mm
Available in one translucency: LT	Available in one translucency: LT
Available in various shades:	Available in BL2, A1, A2, A3, A3.5, A4, B1, B2
Compatible with Wieland milling units or any other units accepting 98.5mm discs where open architecture CAM is used in the design, i.e. 3Shape	Compatible with Wieland milling units or any other units accepting 98.5mm discs where open architecture CAM is used in the design, i.e. 3Shape
The disc delivered unpolished	The subject device is polished on both the top and bottom surfaces to a high gloss. This has no impact on the use, safety or effectiveness of the device.

510(K) SUMMARY

TelioCAD Multi
Rev April 11, 2016

**Technology**

Predicate device (K132937)	Telio CAD Multi
The processing steps for the fabrication of the desired restoration are described in the Instructions for Use.	The processing steps for the fabrication of the desired restoration are described in the Instructions for Use.
Connector dimensions: with 1 pontic: at least 12 mm ² with 2 pontics: at least 12 mm ²	Connector dimensions: with 1 pontic: at least 12 mm ² with 2 pontics: at least 12 mm ²
Polishing, finishing, lining,	Polishing, finishing, lining,
Seating/cementation: Intra-oral cementation using a eugenol-free temporary cement	Seating/cementation: Intra-oral cementation to tooth using a eugenol-free temporary cement
Storage conditions: no special conditions	Storage conditions: no special conditions
Shelf life: no special conditions	Shelf life: no special conditions
Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.	Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.

Materials

Predicate device (K132937)	Telio CAD Multi
PMMA	PMMA

Standards

Predicate device (K132937)	Telio CAD Multi
The device was tested to ISO 10477:2004 and ISO 20795-1 Dentistry – Base Polymers – Part 1: Denture base Polymers	The device was tested to ISO 10477:2004 and ISO 20795-1 Dentistry – Base Polymers – Part 1: Denture base Polymers

Testing Summary: The subject device was not tested for Biocompatibility as no new elements are used in the chemical composition as compared to the predicate device. Biocompatibility evaluation was carried out according to ISO 10993-1 and ISO 7504. No changes have been made which will affect biocompatibility. The device was tested according to ISO 10477:2004 Dentistry – Polymer based crown and bridge materials for Surface finish, Flexural Strength, Bond strength, Water Sorption, Solubility, Shade Consistency and Color stability and the device met all requirements of the standard. The devices was also tested according to ISO 20795-1 :2013 Dentistry – Base Polymers – Part 1: Denture Base Polymers for5 Modulus of Elasticity and Residual monomer and the device met these requirements. Finally, testing according to ISO 179-1:2010 for Charpy toughness, ISO 180:2000 for izod impact strength and ISO 868:2003 for Vickers Hardness (converted from Shore D), was conducted to provide additional insight as to the properties of the materials for its intended use.

Conclusion: The above data and analysis demonstrates that Telio®CAD Multi is substantially equivalent to the predicate device.

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)
K153753

Device Name
TelioCAD Multi

Indications for Use (Describe)

For manufacturing by a CAD/CAM System:

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months
- Provisional inlay and onlays

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

"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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number (if known)
K153753

Device Name
TelioCAD Multi

Indications for Use (Describe)

For manufacturing by a CAD/CAM System:

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months
- Provisional inlay and onlays

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)

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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.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K153753

Date Received by DCC: Dec 29, 2015

Lead Reviewer: Anita Belani

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 the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)

Yes No N/A

1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?

If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."

×

Comments:

2. Is the submission with the appropriate Center?

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 submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."

×

Comments:

3) If a Request for Designation (RFD) 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:

- a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?
- 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?

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 the CBER Product 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 above is no, mark "No." If there was no RFD, mark "N/A."

×

Comments:

4) Is this device type eligible for a 510(k) submission?

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."

X

Comments:

5) Is there a pending PMA for the same device with the same indications for use?

If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.

X

Comments:

6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?

If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) 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 <http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm>

If no clinical studies have been submitted, mark "N/A."

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 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

Organizational Elements*Failure to include these items should not result in an RTA designation.*

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.

	Yes	No	*Page #
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.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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

*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.

Yes

No

N/A

Comment

*Page #

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 (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	×				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	×				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") See recommended format. (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).	×				
4) Submission contains a 510(k) Summary or 510(k) Statement.	×				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k). See recommended format. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).	×				
6) Submission is a Class III 510(k) device.			×		
7) Submission contains clinical data			×		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). 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 from prior submissions for this device are addressed.			×		

B. Device Description

9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.			×		
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	×				
11) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or 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.	×				

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	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. OR Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	×				
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.			×		
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).</i>	×				
b) The identified predicate(s) is consistent throughout the submission (e.g., 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).	×				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] <i>See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.</i>					
a) Indications for Use	×				
b) Technology, including features, materials, and principles of operation	×				
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	×				
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).	×				
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes adequate directions for use (see 21 CFR 801.5) OR - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	×				
16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	×				

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	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").	×				
18) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.			×		
19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			×		
E. Sterilization					
If an <i>in vitro</i> diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked)					
Provided sterile, intended to be single-use					
Requires processing during its use-life					
×					
Non-sterile when used (and no processing required)					
Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
Sterility status not needed for this device (e.g., software-only device)					
Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. Please refer to the guidance document titled " Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling " for additional information.					
20) Assessment of the need for cleaning and subsequent disinfection or sterilization information					
a) Identification of device, and/or accessories, and/or components that are provided sterile.					
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.					
c) Identification of device, and/or accessories, and/or components that are reusable.					
21) If the device, and/or accessory, and/or a component is provided sterile:			×		
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:			×		
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.			×		
F. Shelf Life					
24) Proposed shelf life/expiration date stated OR Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	×				

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	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.						
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.				×		
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). OR Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.			×		×	
Comments: The shelf life section states that shelf life testing has been provided, however, this testing cannot be located. Please provide shelf life testing for this device or state where this information can be located.						
G. Biocompatibility						
If an <i>in vitro</i> diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.						
Submission states that there: (one of the below must be checked)						
☒ Are direct or indirect patient-contacting components.						
☐ Are no direct or indirect patient-contacting components.						
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).						
☐ Patient contact information not needed for this device (e.g., software-only device)						
☐ Patient contact information needed or need unclear						
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.						
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.		×				
28) Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)			×		×	
Comments: Please identify contact classification of the device.						
29) 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						
Submission states that the device: (one of the below must be checked)						
☐ Does contain software/firmware						
☒ Does not contain software/firmware						

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	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.						
Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)						
Software/firmware information not needed for this device (e.g., surgical suture, condom)						
Software/firmware information is needed or need unclear						
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.						
I. Electrical Safety and EMC						
Electrical Safety						
Submission states that the device: (one of the below must be checked)						
Does require electrical safety evaluation						
☒ Does not require electrical safety evaluation						
Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)						
Electrical safety information not needed for this device (e.g., surgical suture, condom)						
Electrical safety information is needed or need unclear						
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.						
EMC						
Submission states that the device: (one of the below must be checked)						
Does require EMC evaluation						
☒ Does not require EMC evaluation						
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)						
EMC information not needed for this device (e.g., surgical suture, condom)						
EMC information is needed or need unclear						
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.						
J. Performance Data - General						
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.						
34) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions.		☒				
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).		☒				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
	Yes	No	N/A	Comment	*Page #
35) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.			X		
36) If literature is referenced in the submission, submission includes:			X		
37) For each completed animal study, the submission provides the following:			X		
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.					
X is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

Decision:☐ Accept☒ Refuse to Accept

If Accept, notify applicant.

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

Digital Signature Concurrence Table

Reviewer Sign-Off

**Anita K.
Belani -A**Digitally signed by Anita K. Belani -
A
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=200081
6413, cn=Anita K. Belani -A
Date: 2015.12.31 16:20:02 -05'00'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.



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.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K153753

Date Received by DCC: Jan 14, 2016

Lead Reviewer: Anita Belani

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 the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)

Yes No N/A

1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?

If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."

×

Comments:

2. Is the submission with the appropriate Center?

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 submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."

×

Comments:

3) If a Request for Designation (RFD) 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:

- a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?
- 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?

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 the CBER Product 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 above is no, mark "No." If there was no RFD, mark "N/A."

×

Comments:

4) Is this device type eligible for a 510(k) submission?

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."

X

Comments:

5) Is there a pending PMA for the same device with the same indications for use?

If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.

X

Comments:

6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?

If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) 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 <http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm>

If no clinical studies have been submitted, mark "N/A."

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 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

Organizational Elements*Failure to include these items should not result in an RTA designation.*

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	×		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	×		
3) All pages of the submission are numbered.	×		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).	×		

Comments:

Elements of a Complete Submission (RTA Items)**(21 CFR 807.87 unless otherwise indicated)**

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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

*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.

Yes

No

N/A

Comment

*Page #

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 (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	×				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	×				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") See recommended format. (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).	×				
4) Submission contains a 510(k) Summary or 510(k) Statement.	×				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) See recommended format. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).	×				
6) Submission is a Class III 510(k) device.			×		
7) Submission contains clinical data			×		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). 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 from prior submissions for this device are addressed.			×		

B. Device Description

9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.			×		
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	×				
11) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or 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.	×				

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	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. OR Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	×				
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.			×		
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online.</i> <i>(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).</i>	×				
b) The identified predicate(s) is consistent throughout the submission (e.g., 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).	×				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] <i>See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.</i>					
a) Indications for Use	×				
b) Technology, including features, materials, and principles of operation	×				
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	×				
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).	×				
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes adequate directions for use (see 21 CFR 801.5) OR - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	×				
16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	×				

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	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.						
17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").		×				
18) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.				×		
19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.				×		
E. Sterilization						
If an <i>in vitro</i> diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.						
Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked)						
Provided sterile, intended to be single-use						
Requires processing during its use-life						
× Non-sterile when used (and no processing required)						
Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)						
	Sterility status not needed for this device (e.g., software-only device)					
	Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. Please refer to the guidance document titled " Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling " for additional information.						
20) Assessment of the need for cleaning and subsequent disinfection or sterilization information						
a) Identification of device, and/or accessories, and/or components that are provided sterile.						
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.						
c) Identification of device, and/or accessories, and/or components that are reusable.						
21) If the device, and/or accessory, and/or a component is provided sterile:				×		
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:				×		
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.				×		
F. Shelf Life						
24) Proposed shelf life/expiration date stated OR Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation		×				

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	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.						
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.				×		
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). OR Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.		×				
G. Biocompatibility						
If an <i>in vitro</i> diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.						
Submission states that there: (one of the below must be checked)						
☒ Are direct or indirect patient-contacting components.						
☐ Are no direct or indirect patient-contacting components.						
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).						
☐	Patient contact information not needed for this device (e.g., software-only device)					
☐	Patient contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.						
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.		×				
28) Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)		×				
29) 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						
Submission states that the device: (one of the below must be checked)						
☐ Does contain software/firmware						
☒ Does not contain software/firmware						
Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)						
☐	Software/firmware information not needed for this device (e.g., surgical suture, condom)					

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	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.						
Software/firmware information is needed or need unclear						
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.						
I. Electrical Safety and EMC						
Electrical Safety						
Submission states that the device: (one of the below must be checked)						
Does require electrical safety evaluation						
☒ Does not require electrical safety evaluation						
Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)						
Electrical safety information not needed for this device (e.g., surgical suture, condom)						
Electrical safety information is needed or need unclear						
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.						
EMC						
Submission states that the device: (one of the below must be checked)						
Does require EMC evaluation						
☒ Does not require EMC evaluation						
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)						
EMC information not needed for this device (e.g., surgical suture, condom)						
EMC information is needed or need unclear						
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.						
J. Performance Data - General						
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.						
34) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions.		☒				
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).		☒				
35) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.				☒		
36) If literature is referenced in the submission, submission includes:				☒		
37) For each completed animal study, the submission provides the following:				☒		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
K. Performance Characteristics - In Vitro Diagnostic Devices Only (Also see <u>21 CFR 809.10(b)(12)</u>)					
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.					
<i>If "is not" is selected, the performance data-related criteria below are omitted from the checklist.</i>					

Decision:☒ Accept☐ Refuse to Accept

If Accept, notify applicant.

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

Digital Signature Concurrence Table

Reviewer Sign-Off

**Anita K.
Belani -A**Digitally signed by Anita K. Belani -
A
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=200081
6413, cn=Anita K. Belani -A
Date: 2016.01.21 21:41:38 -05'00'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.



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

K153753
Ivoclar Vivadent, Inc.
Device Trade Name: Teliocad Multi
Contact Name: Donna Hartnett

DEFICIENCY LIST

Indications for Use

1. You have provided a submission that includes a more detailed indications for use for the subject device than that is contained in the predicate device. You state that the crowns and bridges can be worn for a period of up to 12 months and that the bridges can be fabricated with up to two adjacent pontics. This information is not contained in the indications for use for the predicate device. Please provide an additional predicate device with this verbiage in the indications for use statement as a reference device or remove these details from the existing indications for use statement.
2. You have provided a submission that includes an indications for use statement of the predicate device which states that the material may be manufactured using CAD/CAM technology. However, this verbiage is not contained in the indications for use for the subject device. This information is required for the determination of substantial equivalence. Please provide the method of manufacturing in the indications for use to match that of the predicate device.

Device Description

3. You have provided a device description that includes fluorescent particles; however, have not provided details of the fluorescent particles and has not included the particles in the chemical composition of the device. Please provide more details of the fluorescent particles and to provide a revised composition of the device inclusive of the fluorescent particles.

Administrative Requirements

4. You have stated in your submission that the composition for the subject device are identical to the a previously cleared device K102341 for Vipi Block. Please add K102341 as a reference to the submission and to the 510(k) Summary. Please note that you do not need to provide a comparison to the subject device for every aspect, please just state that this reference device is being added only to demonstrate equivalence in composition and biocompatibility.

Performance Testing – Bench

5. You have provided physical properties testing for this device; however, the physical properties table provided does not include the acceptance criteria for the ISO standards. This information is required for administrative completeness. Please provide the acceptance criteria for the ISO standards for the noted physical properties as a part of the table.



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

K153753
Ivoclar Vivadent, Inc.
Device Trade Name: Teliocad Multi
Contact Name: Donna Hartnett

DEFICIENCY LIST

Indications for Use

1. You have provided a submission that includes a more detailed indications for use for the subject device than that is contained in the predicate device. You state that the crowns and bridges can be worn for a period of up to 12 months and that the bridges can be fabricated with up to two adjacent pontics. This information is not contained in the indications for use for the predicate device. Please provide an additional predicate device with this verbiage in the indications for use statement as a reference device or remove these details from the existing indications for use statement.
2. You have provided a submission that includes an indications for use statement of the predicate device which states that the material may be manufactured using CAD/CAM technology. However, this verbiage is not contained in the indications for use for the subject device. This information is required for the determination of substantial equivalence. Please provide the method of manufacturing in the indications for use to match that of the predicate device.

Device Description

3. You have provided a device description that includes fluorescent particles; however, have not provided details of the fluorescent particles and has not included the particles in the chemical composition of the device. Please provide more details of the fluorescent particles and to provide a revised composition of the device inclusive of the fluorescent particles.

Administrative Requirements

4. You have stated in your submission that the composition for the subject device are identical to the a previously cleared device K102341 for Vipi Block. Please add K102341 as a reference to the submission and to the 510(k) Summary. Please note that you do not need to provide a comparison to the subject device for every aspect, please just state that this reference device is being added only to demonstrate equivalence in composition and biocompatibility.

Performance Testing – Bench

5. You have provided physical properties testing for this device; however, the physical properties table provided does not include the acceptance criteria for the ISO standards. This information is required for administrative completeness. Please provide the acceptance criteria for the ISO standards for the noted physical properties as a part of the table.

January 12, 2016</br></br>

Acceptance Review Notification - Refuse To Accept (RTA)

<p>We have completed the administrative acceptance review of your premarket notification (510(k)) submission K153753. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold. </p>

<p>Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K153753, addressing the elements identified as missing or inconsistent in the attached checklist to:</p>

<p style="padding-left:50">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</p>

<p>FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.</p>

<p>Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission. </p>

<p>Should you have questions about this email, you may contact Anita Belani, the lead reviewer assigned to your 510(k) submission.</p>

<p>For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf. </p>

<p>*** This is a system-generated email notification ***</p>

Ms. Hartnett,

Can you please provide me with a 510(k) Summary that has more details in the comparison of the subject to the predicate device section? A table comparing these would be useful (please provide a little more detail - no test results, and no yes/no type of comparisons). If you could provide by tomorrow, I would appreciate it.

Thanks.

Anita Belani, DDS

Dental Officer

FDA / ODE / DAGRID / DEDB

10903 New Hampshire Avenue

WO66 - RM G321

Silver Spring, MD 20993

Phone: 301-796-3944

Fax: 301-847-8109

Anita.Belani@fda.hhs.gov<mailto:Anita.Belani@fda.hhs.gov>

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<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=436&E=&S=E>

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Food and Drug Administration
CDRH/ODE/DAGID/DEDB
WO66 RMG321
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-3944

Premarket Notification 510(k) Review

Date: March 4, 2016			
Reviewer: Anita Belani			
Subject: Traditional 510(k)# K153753			
Applicant: Ivoclar Vivadent, Inc.		Device Trade Name: Teliocad Multi	
Contact Name: Donna Hartnett		Contact Title: Director Qa/regulatory Affairs	
Correspondent Firm: Ivoclar Vivadent, Inc.		Phone: (716) 691-2260 Email: donna.hartnett@ivoclarvivadent.com	
Received Date: December 29, 2015		Due Date: April 13, 2016	
Pro Code(s): EBG Class: II Reg #: 872.3770		Reg Name: Temporary Crown And Bridge Resin	
Predicate Devices:			
Submission #	Pro Code	Device Trade Name	Owner
K132937	EBG	Harvest Dental Polymer Blocks (zcad, Aurora)	Harvest Dental Products, LLC
Review Summary			
The <i>Telio CAD Multi</i> device consists of polymer (PMMA) blocks for the fabrication of long-term temporaries using CAD/CAM technology. It has the following indications for use: “• Provisional anterior and posterior crowns with a maximum wear period of up to 12 months. • Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months. • Provisional inlay and onlays”			
Recommendation			
I recommend that the Teliocad Multi is/are in need of Additional Information (AINN)			

Review Team

Lead Reviewer

Anita Belani (CDRH/ODE/DAGRID/DEDB)

I. Purpose and History

The submission for the *Telio CAD Multi* consists of a Cover Sheet, Medical Device User Fee Cover Sheet (Form FDA 3601), CDRH Premarket Review Submission Cover Letter, 510(k) Cover Letter, Indications for Use Statement, 510(k) Summary, a Truthful and Accuracy Statement, Declarations of Conformity and Summary Reports, Executive Summary, Device Description, Proposed Labeling, Substantial Equivalence Discussion, Sterilization and Shelf Life, Biocompatibility, and Performance Testing. The primary mode of action for this class II device is through use of polymer (PMMA) blocks for the fabrication of long-term temporaries using CAD/CAM technology.

The submission claims substantial equivalence to (K132937) Harvest Dental Polymer Blocks by Harvest Dental Products, LLC.

II. 510(k) Summary/Statement**510(k) Summary/Statement**

Was a 510(k) Summary or Statement provided?

[Summary](#)

[Undo](#)

The content of the 510(k) Summary will require revisions at the end of the review cycle.

Reviewer Recommendation

The 510(k) Summary/Statement is [not] acceptable. The content of the 510(k) Summary will require revisions at the end of the review cycle.

III. Device/System Description

Device Characteristics		Inadequate Or Marked
Is the intended use or fundamental technology new?	No	☐
Is the device <u>life-supporting</u> or <u>life sustaining</u> ?	No	☐
Are there any <u>direct</u> or <u>indirect patient contacting</u> components?	Yes	☐
• Is the device or a component an <u>implant</u> ?	No	☐
Does the device use software/firmware?	No	☐
Does the device or a component need sterilization (by manufacturer or user)?	No	☐
The device/system uses or is...	a single use device(s) (SUD)	☐
The environment for use of the device/system includes...	Hospital	☐
Is the device a <u>combination product</u> ?	N - Not a Part 3 Combination Product	☐
Is the device/system electrical (<u>battery</u> or <u>wall powered</u>)?	No, the device is not electrical	☐
Check the attributes that are applicable to this submission.		
	Nanotechnology	Reprocessed SUD
	Companion Diagnostic	Medical Counter Measures
Yes	☐	☐
No	☒	☒

Device Characteristics						Inadequate Or Marked
Unknown	☐	☐	☐	☐	☐	
Device Description Table: Summary of important device characteristics						

The sponsor states that the *Telio CAD Multi* device consists of polymer (PMMA) blocks for the fabrication of long-term temporaries using CAD/CAM technology. The discs include fluorescent particles to give the appearance of multi layering for a more favorable esthetic result in the final restoration. Telio CAD Multi restorations are either milled in the dental practice utilizing a chairside design/milling system or in the dental laboratory. The restorations can be polished quickly and efficiently before insertion.

The sponsor states that the PMMA discs have a long-term (12-month) wear period and durable shade stability with lifelike layered appearance. The device is available in 8 shades (BL2, A1, A2, A3, A3.5, A4, B1 and B2) and 4 thicknesses 12mm, 16mm, 20mm and 25mm. They are the standard 98.5 mm in diameter to permit use with the Wieland Select Milling equipment or other equipment which accepts 98.5 mm discs. The sponsor states that the material exhibits high homogeneity due to industrial manufacturing process and temporaries can be easily reproduced using the CAD/CAM Technology.

Device Photo



(b)(4) Proprietary Information

(b)(4) Proprietary Information

Reviewer Recommendation

The Device Description is {not} acceptable. The sponsor will be requested to provide additional information in the S002 responses. Please see below for additional information requested.

The sponsor has provided a device description that includes fluorescent particles to give the appearance of multi layering for a more favorable esthetic result in the final restoration. However, the sponsor has not provided details of the fluorescent particles and has not included the particles in the chemical composition of the device. The sponsor will be requested to provide more details of the fluorescent particles and to provide a revised composition of the device inclusive of the fluorescent particles.

IV. Comparison of Indications for Use to Predicate Devices**Comparison of Indications for Use****Subject**

510(k) #: K153753

Rx/OTC:

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/Newborn
Yes	☐	☐	☐	☒	☐	☐	☐	☐
No	☒	☒	☒	☐	☒	☒	☒	☒
Unknown	☐	☐	☐	☐	☐	☐	☐	☐

Indications for Use:

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays

Predicate(s)

Submission#: K132937

Rx/OTC: Rx

Intended Population: All Pediatric Patients age <= 21

Indications for Use: The harvest dental polymer blocks (zcad) are pmma blanks for manufacturing temporary crowns and bridges by a cad/cam system.

Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Reviewer Recommendation

The Comparison of the Indications for Use is [not] acceptable. The sponsor will be requested to provide revisions to the indications for use in the S002 revisions. Please see below for revisions requested:

The sponsor has provided a more detailed indications for use for the subject device than that is contained in the predicate device. The sponsor states that the crowns and bridges can be worn for a period of up to 12 months and that the bridges can be fabricated with up to two adjacent pontics. The sponsor will be requested to provide an additional predicate device with this verbiage or to remove these details from the indications for use statement. Alternatively, the sponsor may provide data to demonstrate the 12 month longevity or inclusion of two adjacent pontics.

The indications for use of the predicate states that the material may be manufactured using CAD/CAM technology. The verbiage is not contained in subject device. The sponsor will be requested to provide the method of manufacturing in the indications for use to match the predicate device.

V. Comparison of Technology to Predicate Devices

Predicate device (K132937)	Telio CAD Multi
The processing steps for the fabrication of the desired restoration are described in the Instructions for Use.	Same
Connector dimensions: with 1 pontic: at least 12 mm ² with 2 pontics: at least 12 mm ²	Same
Polishing, finishing, lining,	Polishing, finishing, lining,
Seating/cementation: Intra-oral cementation using a eugenol-free temporary cement	Seating/cementation: Intra-oral cementation to tooth: Same
Storage conditions: no special conditions	Storage conditions: no special conditions
Shelf life: no special conditions	Shelf life: no special conditions
Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.	Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.

Reviewer Recommendation

The Comparison of the Technology to Predicate Devices is acceptable.

VI. Labeling

Labeling Review Needed?	Yes	Undo
Usability Consult Needed?	Undo	No

A General Labeling Requirements

General Labeling Requirements		Inadequate or Marked
Is the <u>prescription statement</u> (or "Rx only") included?	Yes	☐
<u>Adequate instructions</u> for OTC use?	Yes	☐
The indications for use are consistent with the IFU page?	Yes	☐
Appropriate contraindications, warnings, precautions and adverse events provided?	Yes	☐
Instructions are in accordance with the guidance (if applicable)?	Inapplicable	☐
Appropriate labeling <u>inside device</u> ?	Yes	☐
Appropriate label/indicator <u>outside device</u> ?	Yes	☐
Appropriate <u>Manual labeling</u> ?	Yes	☐
What <u>MRI safety</u> information does the labeling contain?	Not Evaluated and Not Needed	☐
Labeling Table: A summary of the adequacy of several labeling requirements.		

The proposed labeling contains device labeling, box labeling, as well as instructions for use brochure. The device is imprinted with disc specific information, i.e. disc thickness, shade, lot, date of manufacture, expiration date and product code.

The box labeling contains the trade name of the device, a device description, distribution information, an appropriate prescription statement, symbols with appropriate English translations, shade information, size information, lot number,

The instructions for use contain the device trade name, a device description, distribution information, an appropriate prescription statement. Also contained are the indications for use, contraindications, composition, shades, disc sizes, hazards and warnings, storage, working conditions, design, finishing, hints, and mechanical properties.

Reviewer Recommendation

The Labeling is acceptable.

VII. Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

Telio CAD Multi is intended to be marketed in a non-sterile state and sterilization is not required prior to use. The sponsor has stated that the device has a 10 year shelf life and has provided Long Term Shelf-Life Testing to support the shelf life claim. The shelf life testing is provided in the table below.

(b)(4)

Reviewer Recommendation

Cleaning, Sterilization, Shelf-Life and Reuse descriptions are acceptable. The sponsor has provided real-time shelf life testing for 120 months for the physical properties of water sorption, solubility, and color stability tested to the ISO 10477:2004 standards.

VIII. Biocompatibility

Biocompatibility Review Needed?	☒ Yes	☐ Undo
Biocompatibility Consult Needed?	☐ Undo	☒ No

The sponsor states that the *TelioCAD Multi* is a surface contacting device with contact to mucosal membranes. The contact duration is described as C-Permanent, as the material is indicated as a temporary material with contact to oral tissues for up to 1 year.

(b)(4)

IX. Software/Firmware

This device does not utilize software. Software is not required for a device of this type.

Reviewer Recommendation

The Software is acceptable.

X. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

This device does not contain any electrical, mechanical, or thermal components.

Reviewer Recommendation

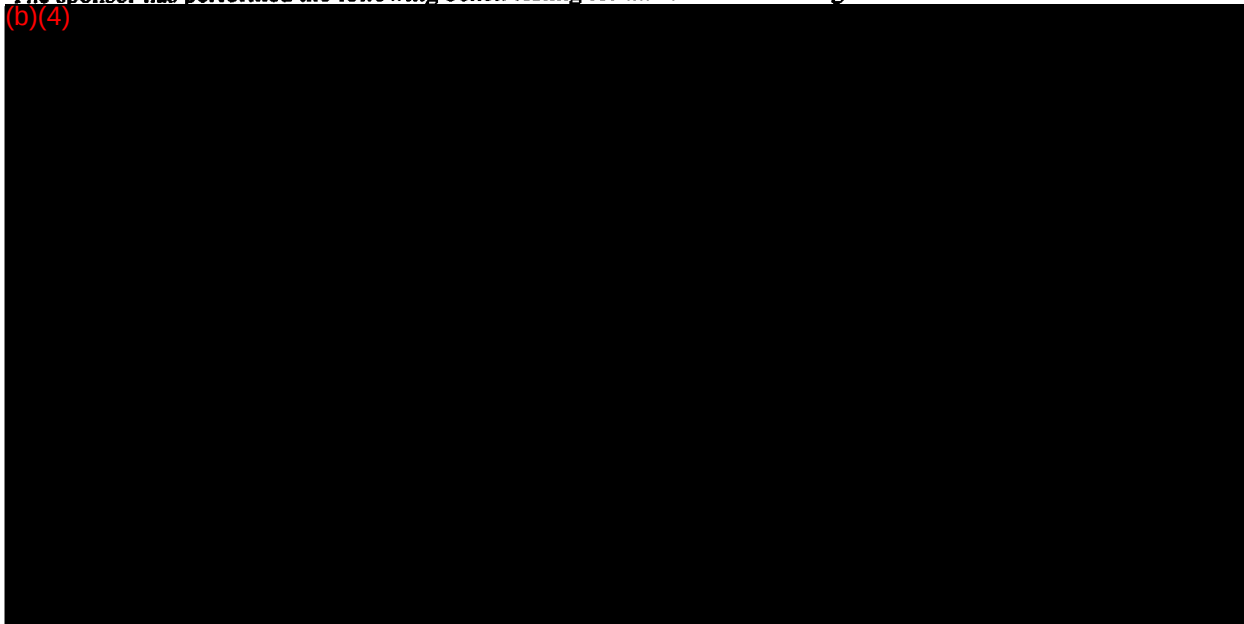
The EMC, EMT and Risk Analysis are acceptable.

XI. Performance Testing

A Bench Testing

The sponsor has performed the following bench testing for this device according to the noted ISO standards:

(b)(4)



B Animal Testing

The submission does not require animal testing, nor is animal testing required for a device of this nature.

C Clinical Testing

The submission does not require clinical testing, nor is clinical testing required for a device of this nature.

Reviewer Recommendation

The Performance Testing [Verification & Validation] is [not] acceptable. The sponsor will be requested to provide revisions to the physical properties table in the S002 responses. Please see below for responses requested:

The sponsor has provided physical properties testing; however, the physical properties table does not include the acceptance criteria for the ISO standards. The sponsor will be requested to provide the acceptance criteria for the ISO standards for the noted physical properties as a part of the table.

Regulatory

Substantial Equivalence Determination	Is the predicate device legally marketed?	Do the devices have the same intended use?
No	☒	☐
Yes	☐	☐

XIII. SE Flowchart Questions

Standards No.	Standards Title	Standards Organization	Standards No.	Standards Title	Standards Organization	Version	Date
10477	Dentistry - Polymer-based crown and bridge materials	ISO	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	ISO	4th Edition	10/15/2009
60793-1	Dentistry - Base polymers - Part 1: Denture base polymers	ISO	60793-1	Dentistry - Base polymers - Part 1: Denture base polymers	ISO	2d Edition	03/01/2013
7403	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry	ISO	7403	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry	ISO	2d Edition	12/15/2008
15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	ISO	15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	ISO	2d Edition	07-01-2012
179-1	Plastics - Determination of Charpy impact properties - Part 1: Non-instrumented impact test	ISO	179-1	Plastics - Determination of Charpy impact properties - Part 1: Non-instrumented impact test	ISO	2d Edition	06/15/2010
180	Plastics - Determination of Izod impact strength	ISO	180	Plastics - Determination of Izod impact strength	ISO	3rd Edition	12/15/2000

XII. References

Predicate device ZCAD (K132937)	Telio CAD Multi
FDA Classification Product Code: EBG	Same
FDA Regulation No. 872.3770	Same

Performance Data / Specification

(b)(4) Proprietary Information

Discussion:

(b)(4)

Indications for use – may need revisions based on responses

Predicate device (K132937)	Telio CAD Multi
510k clearance, Indications for Use Statement: <i>"The Harvest Dental Polymer Blocks (ZCAD) are PMMA blanks for manufacturing temporary crowns and bridges by a CAD/CAM system."</i>	• Provisional anterior and posterior crowns with a maximum wear period of up to 12 months. • Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months. • Provisional inlay and onlays

Discussion:

The changes in the language between the predicate and the subject device only provide clarification as to the use of the device and do not pose a substantial difference.

Device Description

Predicate device (K132937)	Telio CAD Multi
PMMA in the form of polymerized Disc for the fabrication of long-term temporaries by means of the CAD/CAM technology.	PMMA in the form of polymerized discs for the fabrication of long-term temporaries by means of the CAD/CAM technology.
No accessories	No accessories
Product available in different thicknesses	Product available in four different thicknesses 12mm, 16mm, 20mm and 25mm
Available in one translucency: LT	Same
Available in various shades:	Same. Available in BL2, A1, A2, A3, A3.5, A4, B1, B2
Compatible with Wieland milling units or any other units accepting 98.5mm discs where open architecture CAM is used in the design, i.e. 3Shape	Same.
The disc delivered unpolished	The subject device is polished on both the top and bottom surfaces to a high gloss. This has no impact on the use, safety or effectiveness of the device.

Discussion:

The device is the same as the predicate except for the polished surfaces.

Technology

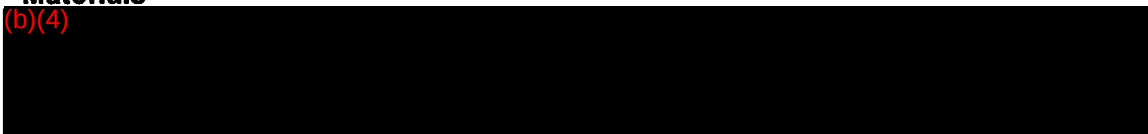
Predicate device (K132937)	Telio CAD Multi
The processing steps for the fabrication of the desired restoration are described in the Instructions for Use.	Same
Connector dimensions: with 1 pontic: at least 12 mm ² with 2 pontics: at least 12 mm ²	Same
Polishing, finishing, lining,	Polishing, finishing, lining,
Seating/cementation: Intra-oral cementation using a eugenol-free temporary cement	Seating/cementation: Intra-oral cementation to tooth: Same
Storage conditions: no special conditions	Storage conditions: no special conditions
Shelf life: no special conditions	Shelf life: no special conditions
Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.	Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.

Discussion:

The technology to prepare temporary restorations is the same as for the predicate device.

Materials

(b)(4)



(b)(4)

Discussion:

The material is the same as the predicate device. No additional biocompatibility testing is required.

Standards

Predicate device (K132937)	Telio CAD Multi
The device was tested to ISO 10477:2004 and ISO 20795-1 Dentistry – Base Polymers – Part 1: Denture base Polymers	The device was tested to ISO 10477:2004 and ISO 20795-1 Dentistry – Base Polymers – Part 1: Denture base Polymers

Discussion:

Both the subject and the predicate device have been tested with the same Standard.

XIV. Original Deficiencies**Indications for Use**

1. You have provided a submission that includes a more detailed indications for use for the subject device than that is contained in the predicate device. You state that the crowns and bridges can be worn for a period of up to 12 months and that the bridges can be fabricated with up to two adjacent pontics. This information is not contained in the indications for use for the predicate device. Please provide an additional predicate device with this verbiage in the indications for use statement as a reference device or remove these details from the existing indications for use statement.
2. You have provided a submission that includes an indications for use statement of the predicate device which states that the material may be manufactured using CAD/CAM technology. However, this verbiage is not contained in the indications for use for the subject device. This information is required for the determination of substantial equivalence. Please provide the method of manufacturing in the indications for use to match that of the predicate device.

Device Description

3. You have provided a device description that includes fluorescent particles; however, have not provided details of the fluorescent particles and has not included the particles in the chemical composition of the device. Please provide more details of the fluorescent particles and to provide a revised composition of the device inclusive of the fluorescent particles.

Administrative Requirements

4. You have stated in your submission that the composition for the subject device are identical to the a previously cleared device (b)(4). Please add K102341 as a reference to the submission and to the 510(k) Summary. Please note that you do not need to provide a comparison to the subject device for every aspect, please just state that this reference device is being added only to demonstrate equivalence in composition and biocompatibility.

Performance Testing – Bench

5. You have provided physical properties testing for this device; however, the physical properties table provided does not include the acceptance criteria for the ISO standards. This information is required for administrative completeness. Please provide the acceptance criteria for the ISO standards for the noted physical properties as a part of the table.

XV. Contact History

On 12/29/15, the file was assigned to the lead reviewer for an administrative review.

On 1/12/16 the file was RTA1.

On 1/14/16, the file was assigned to the lead reviewer for an administrative review.

On 1/28/16 the file was RTAA.

On 3/4/16, the file was placed on hold pending the sponsor's responses to the noted deficiencies.

Digital Signature Concurrence Table	
Reviewer Sign-Off	



Food and Drug Administration
CDRH/ODE/DAGID/DEDB
WO66 RMG321
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-3944

Premarket Notification 510(k) Review

Date: April 7, 2016									
Reviewer: Anita Belani									
Subject: Traditional 510(k)# K153753									
Applicant: Ivoclar Vivadent, Inc.	Device Trade Name: Teliocad Multi								
Contact Name: Donna Hartnett	Contact Title: Director Qa/regulatory Affairs								
Correspondent Firm: Ivoclar Vivadent, Inc.	Phone: (716) 691-2260 Email: donna.hartnett@ivoclarvivadent.com								
Received Date: December 29, 2015	Due Date: April 13, 2016								
Pro Code(s): EBG Class: II Reg #: 872.3770	Reg Name: Temporary Crown And Bridge Resin								
Predicate Devices:									
<table border="1"><thead><tr><th>Submission #</th><th>Pro Code</th><th>Device Trade Name</th><th>Owner</th></tr></thead><tbody><tr><td>K132937</td><td>EBG</td><td>Harvest Dental Polymer Blocks (zcad, Aurora)</td><td>Harvest Dental Products, LLC</td></tr></tbody></table>	Submission #	Pro Code	Device Trade Name	Owner	K132937	EBG	Harvest Dental Polymer Blocks (zcad, Aurora)	Harvest Dental Products, LLC	
Submission #	Pro Code	Device Trade Name	Owner						
K132937	EBG	Harvest Dental Polymer Blocks (zcad, Aurora)	Harvest Dental Products, LLC						
Review Summary									
The subject device is a Temporary Crown And Bridge Resin with the following Indications for Use: " For manufacturing by a CAD/CAM System - o Provisional anterior and posterior crowns with a maximum wear period of up to 12 months. - o Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months. - o Provisional inlay and onlays" It is for Rx use. The <i>Telio CAD Multi</i> device consists of polymer (PMMA) blocks for the fabrication of long-term temporaries using CAD/CAM technology. It has the following indications for use: • Provisional anterior and posterior crowns with a maximum wear period of up to 12 months. • Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months. • Provisional inlay and onlays"									
Recommendation									
I recommend that the Teliocad Multi is/are Substantially Equivalent (SESE)									

Review Team

Lead Reviewer

Anita Belani (CDRH/ODE/DAGRID/DEDB)

I. Purpose and History

The submission for the *Telio CAD Multi* consists of a Cover Sheet, Medical Device User Fee Cover Sheet (Form FDA 3601), CDRH Premarket Review Submission Cover Letter, 510(k) Cover Letter, Indications for Use Statement, 510(k) Summary, a Truthful and Accuracy Statement, Declarations of Conformity and Summary Reports, Executive Summary, Device Description, Proposed Labeling, Substantial Equivalence Discussion, Sterilization and Shelf Life, Biocompatibility, and Performance Testing. The primary mode of action for this class II device is through use of polymer (PMMA) blocks for the fabrication of long-term temporaries using CAD/CAM technology.

The submission claims substantial equivalence to (K132937) Harvest Dental Polymer Blocks by Harvest Dental Products, LLC.

II. 510(k) Summary/Statement**510(k) Summary/Statement**

Was a 510(k) Summary or Statement provided?

[Summary](#)

[Undo](#)

The content of the 510(k) Summary is acceptable.

Reviewer Recommendation

The 510(k) Summary/Statement is acceptable.

III. Device/System Description

Device Characteristics		Inadequate Or Marked		
Is the intended use or fundamental technology new?	No	☐		
Is the device <u>life-supporting or life sustaining</u> ?	No	☐		
Are there any <u>direct or indirect patient contacting</u> components?	Yes	☐		
• Is the device or a component an <u>implant</u> ?	No	☐		
Does the device use software/firmware?	No	☐		
Does the device or a component need sterilization (by manufacturer or user)?	No	☐		
The device/system uses or is...	a single use device(s) (SUD)	☐		
The environment for use of the device/system includes...	Hospital	☐		
Is the device a <u>combination product</u> ?	N - Not a Part 3 Combination Product	☐		
Is the device/system electrical (<u>battery or wall powered</u>)?	No, the device is not electrical	☐		
Check the attributes that are applicable to this submission.				
	Nanotechnology	Reprocessed SUD	Companion Diagnostic	Medical Counter Measures
Yes	☐	☐	☐	☐
No	☒	☒	☒	☒

Device Characteristics					Inadequate Or Marked
Unknown	☐	☐	☐	☐	
Device Description Table: Summary of important device characteristics					

The sponsor states that the *Telio CAD Multi* device consists of polymer (PMMA) blocks for the fabrication of long-term temporaries using CAD/CAM technology. The discs include fluorescent particles to give the appearance of multi layering for a more favorable esthetic result in the final restoration. Telio CAD Multi restorations are either milled in the dental practice utilizing a chairside design/milling system or in the dental laboratory. The restorations can be polished quickly and efficiently before insertion.

The sponsor states that the PMMA discs have a long-term (12-month) wear period and durable shade stability with lifelike layered appearance. The device is available in 8 shades (BL2, A1, A2, A3, A3.5, A4, B1 and B2) and 4 thicknesses 12mm, 16mm, 20mm and 25mm. They are the standard 98.5 mm in diameter to permit use with the Wieland Select Milling equipment or other equipment which accepts 98.5 mm discs. The sponsor states that the material exhibits high homogeneity due to industrial manufacturing process and temporaries can be easily reproduced using the CAD/CAM Technology.

Device Photo



Composition

(b)(4) Proprietary Information

(b)(4)

(b)(4)

Reviewer Recommendation

The Device Description is {not} acceptable. The sponsor will be requested to provide additional information in the S002 responses. Please see below for additional information requested.

The sponsor has provided a device description that includes fluorescent particles to give the appearance of multi layering for a more favorable esthetic result in the final restoration. However, the sponsor has not provided details of the fluorescent particles and has not included the particles in the chemical composition of the device. The sponsor will be requested to provide more details of the fluorescent particles and to provide a revised composition of the device inclusive of the fluorescent particles.

- In S002, the sponsor states that the fluorescent particles are added for esthetics (gloss) and states the location in the submission where the device description included a chemical composition including the particles. Please see chemical composition listed in the device description section above. This response is acceptable.

IV. Comparison of Indications for Use to Predicate Devices**Comparison of Indications for Use****Subject**

510(k) #: K153753

Rx/OTC: Rx

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/Newborn
Yes	☐	☐	☐	☒	☐	☐	☐	☐
No	☒	☒	☒	☐	☒	☒	☒	☒
Unknown	☐	☐	☐	☐	☐	☐	☐	☐

Indications for Use:

For manufacturing by a CAD/CAM System

- Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.
- Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.
- Provisional inlay and onlays

Predicate(s)

Submission#: K132937

Rx/OTC: Rx

Intended Population: All Pediatric Patients age <= 21

Indications for Use: The harvest dental polymer blocks (zcad) are pmma blanks for manufacturing temporary crowns and bridges by a cad/cam system.

Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Reviewer Recommendation

The Comparison of the Indications for Use is [not] acceptable. The sponsor will be requested to provide revisions to the indications for use in the S002 revisions. Please see below for revisions requested:

The sponsor has provided a more detailed indications for use for the subject device than that is contained in the predicate device. The sponsor states that the crowns and bridges can be worn for a period of up to 12 months and that the bridges can be fabricated with up to two adjacent pontics. The sponsor will be requested to provide an additional predicate device with this verbiage or to remove these details from the indications for use statement. Alternatively, the sponsor may provide data to demonstrate the 12 month longevity or inclusion of two adjacent

pontics.

The indications for use of the predicate states that the material may be manufactured using CAD/CAM technology. The verbiage is not contained in subject device. The sponsor will be requested to provide the method of manufacturing in the indications for use to match the predicate device.

- In S002, the sponsor has provided a revised indications adding the method of manufacturing (CAD/CAM technology). The sponsor has also added a reference device to the 510(k) Summary K150432 to support the indications for a 12 month wear period as well as fabrication with up to two adjacent pontics. Please see the revised Indications for Use above for the subject device. This response is acceptable.

V. Comparison of Technology to Predicate Devices

Predicate device (K132937)	Telio CAD Multi
The processing steps for the fabrication of the desired restoration are described in the Instructions for Use.	Same
Connector dimensions: with 1 pontic: at least 12 mm ² with 2 pontics: at least 12 mm ²	Same
Polishing, finishing, lining,	Polishing, finishing, lining,
Seating/cementation: Intra-oral cementation using a eugenol-free temporary cement	Seating/cementation: Intra-oral cementation to tooth: Same
Storage conditions: no special conditions	Storage conditions: no special conditions
Shelf life: no special conditions	Shelf life: no special conditions
Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.	Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.

Reviewer Recommendation

The Comparison of the Technology to Predicate Devices is acceptable.

VI. Labeling

Labeling Review Needed?	<input checked="" type="button" value="Yes"/>	Undo
Usability Consult Needed?	Undo	<input checked="" type="button" value="No"/>

A General Labeling Requirements

General Labeling Requirements		Inadequate or Marked
Is the <u>prescription statement</u> (or "Rx only") included?	Yes	☐
The indications for use are consistent with the IFU page?	Yes	☐
Appropriate contraindications, warnings, precautions and adverse events provided?	Yes	☐
Instructions are in accordance with the guidance (if applicable)?	Inapplicable	☐

Appropriate labeling <u>inside device</u> ?	Yes	☐
Appropriate label/indicator <u>outside device</u> ?	Yes	☐
Appropriate <u>Manual labeling</u> ?	Yes	☐
What <u>MRI safety</u> information does the labeling contain?	Not Evaluated and Not Needed	☐
Labeling Table: A summary of the adequacy of several labeling requirements.		

The proposed labeling contains device labeling, box labeling, as well as instructions for use brochure. The device imprinted with Disc specific information, i.e. disc thickness, shade, lot, date of manufacture, expiration date and product code.

The box labeling contains the trade name of the device, a device description, distribution information, an appropriate prescription statement, symbols with appropriate English translations, shade information, size information, lot number,

The instructions for use contain the device trade name, a device description, distribution information, an appropriate prescription statement. Also contained are the indications for use, contraindications, composition, shades, disc sizes, hazards and warnings, storage, working conditions, design, finishing, hints, and mechanical properties.

Reviewer Recommendation

The Labeling is acceptable.

VII. Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

Telio CAD Multi is intended to be marketed in a non-sterile state and sterilization is not required prior to use. The sponsor has stated that the device has a 10 year shelf life and has provided Long Term Shelf-Life Testing to support the shelf life claim. The shelf life testing is provided in the table below.

(b)(4)

Reviewer Recommendation

Cleaning, Sterilization, Shelf-Life and Reuse descriptions are acceptable. The sponsor has provided real-time shelf life testing for 120 months for the physical properties of water sorption, solubility, and color stability tested to the ISO 10477:2004 standards.

VIII. Biocompatibility

Biocompatibility Review Needed?	Yes	☐
Biocompatibility Consult Needed?	☐	No

The sponsor states that the *TelioCAD Multi* is a surface contacting device with contact to mucosal membranes. The contact duration is described as C-Permanent, as the material is indicated as a temporary material with contact to oral tissues for up to 1 year.

Reviewer Recommendation

The Biocompatibility is acceptable. The sponsor states that the composition and indications for use are identical to the a previously cleared device (b)(4)

(b)(4) The sponsor will be requested to add this device as a reference device to the submission.

- In S002, the sponsor has added K102341 as a reference to the submission and to the 510(k) Summary. The sponsor has stated that this reference device is being added only to demonstrate equivalence in composition and biocompatibility. This response is acceptable.

IX. Software/Firmware

This device does not utilize software. Software is not required for a device of this type.

Reviewer Recommendation

The Software is acceptable.

X. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

This device does not contain any electrical, mechanical, or thermal components.

Reviewer Recommendation

The EMC, EMT and Risk Analysis are acceptable.

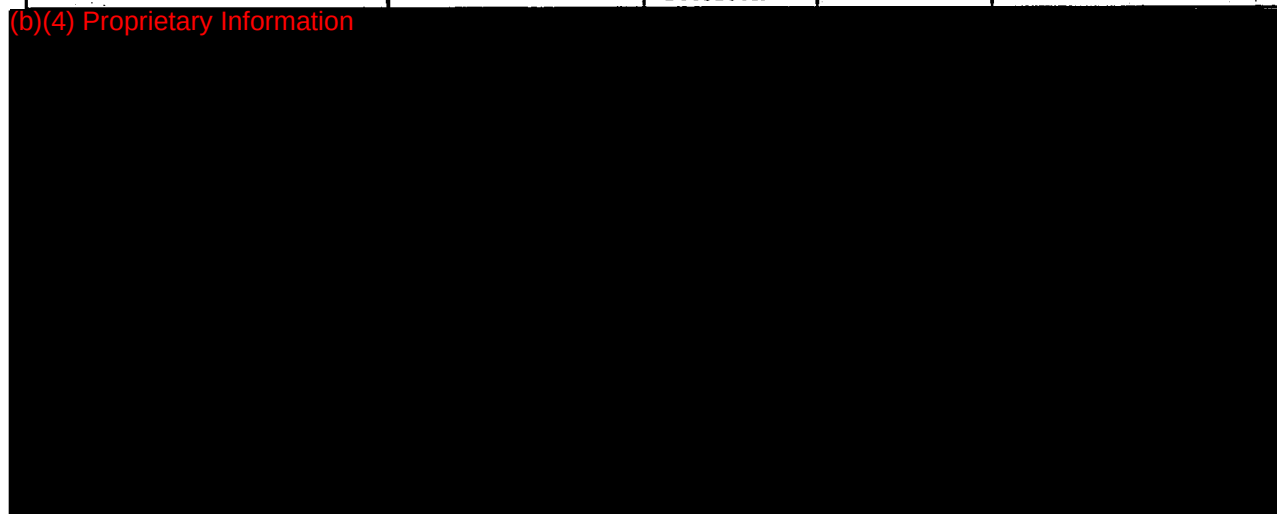
XI. Performance Testing

A Bench Testing

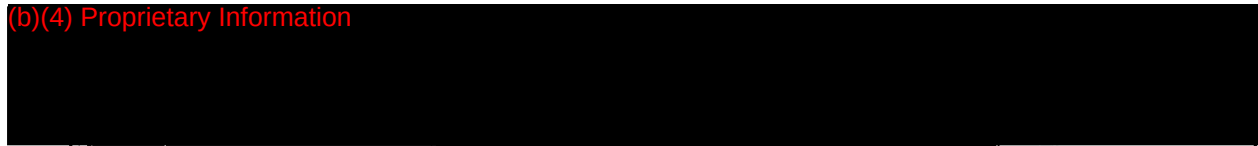
The sponsor has performed the following bench testing for this device according to the noted ISO standards:

Property	Standard	Acc. Criteria	Value	Measurement
----------	----------	---------------	-------	-------------

(b)(4) Proprietary Information



(b)(4) Proprietary Information



B Animal Testing

The submission does not require animal testing, nor is animal testing required for a device of this nature.

C Clinical Testing

The submission does not require clinical testing, nor is clinical testing required for a device of this nature.

Reviewer Recommendation

The Performance Testing [Verification & Validation] is [not] acceptable. The sponsor will be requested to provide revisions to the physical properties table in the S002 responses. Please see below for responses requested:

The sponsor has provided physical properties testing; however, the physical properties table does not include the acceptance criteria for the ISO standards. The sponsor will be requested to provide the acceptance criteria for the ISO standards for the noted physical properties as a part of the table.

- In S002, the sponsor has provided an updated physical properties chart with the acceptance criteria included in the chart. Please see physical properties table in Bench Testing section above for updated physical properties testing chart. This response is acceptable.

XII. References

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 10477	ISO	Dentistry - Polymer-based crown and bridge materials	2d Edition	10/01/2004
2	ISO 10993-1	ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	4th Edition	10/15/2009
3	ISO 20795-1	ISO	Dentistry - Base Polymers - Part 1: Denture Base Polymers	2d Edition	03/01/2013
4	ISO 7405	ISO	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry	2d Edition	12/15/2008
6	ISO 15223-1	ISO	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	2d Edition	07-01-2012
6	ISO 179-1	ISO	Plastics - Determination of Charpy impact properties - Part 1: Non-instrumented impact test	2d Edition	06/15/2010
7	ISO 180	ISO	Plastics - Determination of Izod impact strength	3rd Edition	12/15/2000

XIII. SE Flowchart Questions

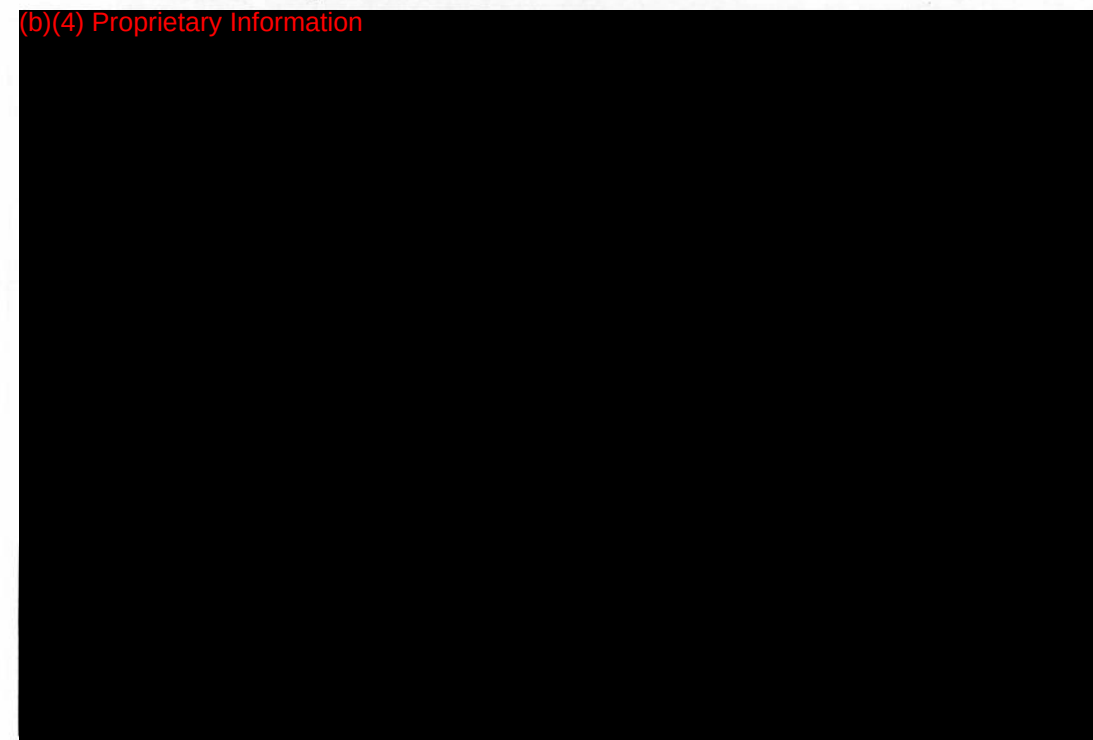
Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☒	☐
Please explain how the intended use of the subject device is similar to or different from the predicate device: Both are used for manufacturing temporary restorations using CAD/CAM manufacturing.		
Do the devices have the same technological characteristics?	☒	☐

Regulatory

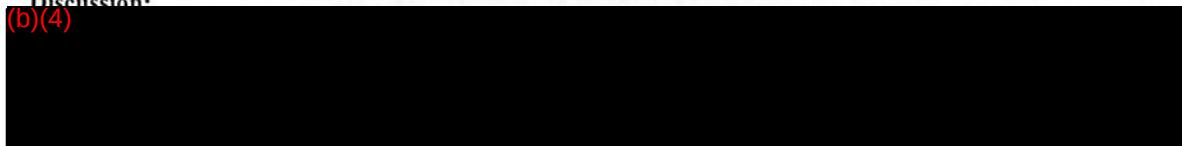
Predicate device ZCAD (K132937)	Telio CAD Multi
FDA Classification Product Code: EBG	Same
FDA Regulation No. 872.3770	Same

Performance Data / Specification

(b)(4) Proprietary Information

**Discussion:**

(b)(4)

**Indications for use**

Predicate device (K132937)	Telio CAD Multi
510k clearance, Indications for Use Statement: <i>"The Harvest Dental Polymer Blocks (ZCAD) are PMMA blanks for manufacturing temporary crowns and bridges by a CAD/CAM system."</i>	• For manufacturing with a CAD/CAM system • Provisional anterior and posterior crowns with a maximum wear period of up to 12 months. • Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months. • Provisional inlay and onlays

Discussion:

(b)(4)

Device Description

Predicate device (K132937)	Telio CAD Multi
PMMA in the form of polymerized Disc for the fabrication of long-term temporaries by means of the CAD/CAM technology.	PMMA in the form of polymerized discs for the fabrication of long-term temporaries by means of the CAD/CAM technology.
No accessories	No accessories
Product available in different thicknesses	Product available in four different thicknesses 12mm, 16mm, 20mm and 25mm
Available in one translucency: LT	Same
Available in various shades:	Same. Available in BL2, A1, A2, A3, A3.5, A4, B1, B2
Compatible with Wieland milling units or any other units accepting 98.5mm discs where open architecture CAM is used in the design, i.e. 3Shape	Same.
The disc delivered unpolished	The subject device is polished on both the top and bottom surfaces to a high gloss. This has no impact on the use, safety or effectiveness of the device.

Discussion:

The device is the same as the predicate except for the polished surfaces.

Technology

Predicate device (K132937)	Telio CAD Multi
The processing steps for the fabrication of the desired restoration are described in the Instructions for Use.	Same
Connector dimensions: with 1 pontic: at least 12 mm ² with 2 pontics: at least 12 mm ²	Same
Polishing, finishing, lining,	Polishing, finishing, lining,
Seating/cementation: Intra-oral cementation using a eugenol-free temporary cement	Seating/cementation: Intra-oral cementation to tooth: Same
Storage conditions: no special conditions	Storage conditions: no special conditions
Shelf life: no special conditions	Shelf life: no special conditions
Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.	Sterilization: Device is delivered non-sterile and no sterilization is recommended for use.

Discussion:

The technology to prepare temporary restorations is the same as for the predicate device.

Materials

(b)(4)

Discussion:

The material is the same as the predicate device. No additional biocompatibility testing is required.

Standards

Predicate device (K132937)	Telio CAD Multi
The device was tested to ISO 10477:2004 and ISO 20795-1 Dentistry – Base Polymers – Part 1: Denture base Polymers	The device was tested to ISO 10477:2004 and ISO 20795-1 Dentistry – Base Polymers – Part 1: Denture base Polymers

Discussion:

Both the subject and the predicate device have been tested with the same Standard.

XIV. Original Deficiencies**Indications for Use**

1. You have provided a submission that includes a more detailed indications for use for the subject device than that is contained in the predicate device. You state that the crowns and bridges can be worn for a period of up to 12 months and that the bridges can be fabricated with up to two adjacent pontics. This information is not contained in the indications for use for the predicate device. Please provide an additional predicate device with this verbiage in the indications for use statement as a reference device or remove these details from the existing indications for use statement.
2. You have provided a submission that includes an indications for use statement of the predicate device which states that the material may be manufactured using CAD/CAM technology. However, this verbiage is not contained in the indications for use for the subject device. This information is required for the determination of substantial equivalence. Please provide the method of manufacturing in the indications for use to match that of the predicate device.

Device Description

3. You have provided a device description that includes fluorescent particles; however, have not provided details of the fluorescent particles and has not included the particles in the chemical composition of the device. Please provide more details of the fluorescent particles and to provide a revised composition of the device inclusive of the fluorescent particles.

Administrative Requirements

4. You have stated in your submission that the composition for the subject device are identical to the a previously cleared device K102341 for Vipi Block. Please add K102341 as a reference to the submission and to the 510(k) Summary. Please note that you do not need to provide a comparison to the subject device for every aspect, please just state that this reference device is being added only to demonstrate equivalence in composition and biocompatibility.

