



Food and Drug Administration  
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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.

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" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

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

You may obtain other general information on your responsibilities under the Act from the Division of 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

## 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.

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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>	<ul style="list-style-type: none"> <li>• Provisional anterior and posterior crowns with a maximum wear period of up to 12 months.</li> <li>• Provisional anterior and posterior bridges with up to two adjacent pontics for a maximum wear period of up to 12 months.</li> <li>• Provisional inlay and onlays</li> </ul>
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 <sup>2</sup> with 2 pontics: at least 12 mm <sup>2</sup>	Connector dimensions: with 1 pontic: at least 12 mm <sup>2</sup> with 2 pontics: at least 12 mm <sup>2</sup>
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.