K130436

510(K) SUMMARY

MULTILINK HYBRID ABUTMENT CEMENT

ivoclar vivadent
passion vision innovation

Contact: Donna Marie Hartnett

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

Date Prepared: August 20, 2013

AUG 2 0 2013

Proprietary Name: Multilink Hybrid Abutment Cement

Classification Name: Dental Cement (872.3275) (Classification Code EMA)

Predicate Devices: Multilink Implant (K090704)

Device Description: Multilink® Hybrid Abutment is a self-curing luting composite for the extraoral, permanent cementation of ceramic structures made of lithium disilicate glass-ceramic (LS2) or zirconium oxide on titanium/titanium alloy or zirconium oxide bases (e.g. abutment or adhesive basis) in the fabrication of hybrid abutments or hybrid abutment crowns.

The predicate device to which Multilink Hybrid Abutment cement has been compared is Multilink Implant (K090704). For this application, Multilink Hybrid Abutment cement has been compared to its predicate with regard to chemical composition, performance data and indications for use. The comparison shows that Multilink Hybrid Abutment is substantially equivalent to the predicate device.

Intended Use: Extraoral, permanent cementation of ceramic structures made of lithium disilicate glass ceramic (LS_2) or zirconium oxide on titanium/titanium alloy or zirconium oxide bases.

Guidance Document: The submission was prepared in accordance with FDA Guidance document entitled Dental Composite Resin Devices – Premarket Notification (510K) Submissions dated October 26, 2005.

Technological Characteristics: The device design, i.e. delivery form, and intended use of Multilink Hybrid Abutment cement and the predicate device are the same except Multilink Hybrid Abutment material is used extra-orally which the predicate is used intra-orally. The composition of the subject device has been modified from the predicate.

Testing Summary: The device was tested in accordance with ISO 4049:2000 for Polymer based dental restorative materials for Water Absorption, Water solubility, radiopacity, Flexural Strength, Modulus of Elasticity, Compressive Strength and Shear Bond Strength and the results from testing demonstrates that Multilink Hybrid Abutment is substantially equivalent to the predicate device. Biocompatibility testing and evaluation was also carried out according to ISO 10993.

We will notify the FDA after completion of the real-time testing of the proposed device if the shelf life differs than the 24 months claimed. Multilink Automix – K123397.

CONCLUSION: The above data and analysis demonstrates that Multilink Hybrid Abutment Cement is substantially equivalent to the predicate device.

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

August 20, 2013

Ivoclar Vivadent, AG
C/O Ms. Donna Marie Hartnett
Director Quality Assurance Regulatory Affairs
175 Pineview Drive
AMHERST NY 14228

Re: K130436
Trade/Device Name: Multilink Hybrid Abutment Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: July 16, 2013
Received: July 22, 2013

Dear Ms. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division 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): K130436

Device Name: Multilink Hybrid Abutment Cement

Indications For Use:

Extraoral, permanent cementation of ceramic structures made of lithium disilicate glass ceramic (LS_2) or zirconium oxide on titanium/titanium alloy or zirconium oxide bases.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Andrew I. Steen -S
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
)ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

10(k) Number: K130436