JAN - 3 2014

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CONFIDENTIAL

SECTION 6

510(k) Summary

Proprietary Name	Fusion Single Link
K Number	K132923
Date Prepared	December 3, 2013
Submitter	Angelus Industria de Productos Odontologicos Waldir Landgraf, 101 Londrina, Brazil 86031-3200 Telephone: +55 43 2101 3200
Official Contact	Tara Conrad TechLink International Consulting 18851 NE 29th Avenue Suite 720 Aventura, FL 33180 TEL- (305) 377-0077
Common Name:	Resin Tooth Bonding Agent
Trade Name:	Fusion Single Link
Classification:	Class II
Product Code:	KLE
Classification Panel:	Dental
Regulation Numbers:	21 CFR 872.3200
Substantial Equivalence:	K962785 3M Dent System (Single Bond) by 3M Company

Description of Proposed Device

The Fusion Single Link by Angelus is a versatile system for dental bonding. It is a one-bottle adhesive system, indicated for restorations, adhesive cementation of indirect restorations (cast metal, porcelain and composite resin veneers) and intraradicular posts (cast metal and prefabricated in metal or fiber). It can also be used for the bonding of orthodontic brackets, and for the repair of porcelain restorations.

Indications for Use

Bonding all classes of direct composite restorations as well as for indirect procedures involving metal, porcelain, or composite crowns, inlays or onlays. The Angelus products multi-purpose systems also bond amalgam and self-cure composite can be used to bond orthodontic brackets to enamel.

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Device Comparison Table

	Subject Device	Predicate Device
	Fusion Single Link by Angelus	K962785 3M Dent System (Single Bond) by 3M Company
Indications for use	Bonding all classes of direct composite restorations as well as for indirect procedures involving metal, porcelain, or composite enamel.	Bonding all classes of direct composite restorations as well as for indirect procedures involving metal, porcelain, or composite crowns, inlays or onlays. The 3m Dent System also bonds amalgam and self-cure composite can be used to bond orthodontic brackets to enamel and root desensitization
Delivery System	Unit Dose, Vial	Unit Dose, Vial
Material	Light Cure	Light Cure
Product Type	Adhesive	Adhesive
Film thickness	Enamel adhesive layer (μm): 8.2(2.40) Dentin adhesive layer (μm): 8.4(2.6)	Enamel adhesive layer (μm): 6.40(2.80) Dentin adhesive layer (μm): 4.22(1.25)
Application time	Total time 60 second Light cure time 12 seconds	Total time 57 second Light cure time 10 seconds
Bond to Dentin	37 MPa	45 MPa

Substantial Equivalence

The predicate and subject devices are substantially equivalent because they are both adhesive systems. They have the same intended use and similar materials. They both utilize materials that will polymerize upon exposure to visible light from a dental curing light. The systems act as both a primer and an adhesive.

Biocompatibility

Single Link has the same composition and applications as its predicate. This product is for permanent contact with tissue, bone and dentin.

Performance Data

Based on performance data according the ISO/TS 11405: 2003, it was found that the average strength and average resistance of the two devices are substantially equivalent.

ISO/TS 11405: 2003- Dental materials -- testing of adhesion to tooth structure

ISO 11405:2003 gives guidance on substrate selection, storage and handling as well as essential characteristics of different test methods for quality testing of the adhesive bond between restorative dental materials and tooth structure, i.e. enamel and dentine. It specifies two bond strength measurements tests (tensile and shear), a test for measurement of marginal gaps around fillings and a microleakage test, as well as giving recommendations on clinical usage tests for such materials. It also presents

some specific test methods for bond strength measurements.

Conclusion

Based on chemical composition, testing, and indications for use, Angelus has concluded that he subject and predicate devices are substantially equivalent that the subject device does not raise any safety or effectiveness concerns. Therefore the devices have been found to be substantially equivalent.

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

January 3, 2014

TechLink International Consulting
Ms. Tara Conrad
Regulatory Affairs Manager
18851 NE 29TH Avenue Suite 720
Aventura, FL 33180

Re: K132923
Trade/Device Name: Fusion Single Link
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: October 9, 2013
Received: October 10, 2013

Dear Ms. Conrad:

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

Erin I. Keith, M.S.
Acting 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 Statement

Device Name: Fusion Single Link

510(k) Number: K132923

Indications for Use:

Bonding all classes of direct composite restorations as well as for indirect procedures involving metal, porcelain, or composite crowns, inlays or onlays. The Angelus products multi-purpose systems also bond amalgam and self-cure composite can be used to bond orthodontic brackets to enamel.

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

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Concurrence of CDRH, Office of Device Evaluation
(ODE) Page 1 of 1

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