



Food and Drug Administration
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June 17, 2015

Tokuyama Dental Corporation
c/o Mr. Keith A. Barritt
Fish & Richardson P.C.
1425 K Street NW Suite 1100
Washington, DC 20005

Re: K150727

Trade/Device Name: ESTECEM
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: March 13, 2015
Received: March 20, 2015

Dear Mr. Barritt:

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,

 Tina
Kiang -S

for 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)

K150727

Device Name

ESTECEM

Indications for Use (Describe)

The ESTECEM device is an adhesive resin cement for the cementation of crowns, bridges, inlays, and onlays made of glass/oxide ceramics (porcelain, zirconia and alumina), metals/alloys (precious and non-precious) and resin materials including inorganic filler (composite materials). The ESTECEM device is indicated for:

- Repair of fractured porcelain fused to metal crowns and all ceramic restorations
- Cementation of veneers
- Cementation of adhesion bridges
- Cementation of metal or resin cores, metal or glass-fiber posts

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
Tokuyama Dental Corporation

ESTECEM Adhesive Resin Cement

The following information is provided pursuant to 21 CFR 807.92.

807.92(a)(1): Submitter's Name and Address

(i) 510(k) Submitter

Tokuyama Dental Corporation
38-9 Taitou 1-chome, Taitou-ku
Tokyo 110-0016
Japan
Phone: 011-81-3-3835-2261

(ii) 510(k) Submitter Contact

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W., Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331
Email: barritt@fr.com

(iii) Preparation Date

March 9, 2015

807.92(a)(2): Name of Device

Trade or Proprietary Name:	ESTECEM
Common Name:	dental adhesive resin cement
Classification Name:	cement, dental
Product Code:	EMA
Regulation:	21 CFR 872.3275

807.92(a)(3): Predicate Devices

The ESTECCEM adhesive resin cement device is substantially equivalent for purposes of FDA medical device regulations to multiple predicate devices with respect to performance and biocompatibility, namely to the Primary Predicate BISTITE II DC (K#011685, Health Canada license no. 60061) and Reference Devices CLEARFIL ESTHETIC CEMENT & DC BOND (K#062410, Health Canada license no. 73128); MULTILINK AUTOMIX (K#123397, Health Canada license no. 79221); and DUOLINK II (K#101787, Health Canada license no. 30968). Additional information regarding the predicate devices appears at the end of this 510(k) Summary.

807.92(a)(4): Device Description

The ESTECCEM device is a dual-cure (light and/or self-cure), radiopaque, adhesive resin cement system with excellent handling, esthetic and adhesive properties to teeth and all prosthetic materials. The main components of the ESTECCEM device are (1) the paste (A/B) and (2) primer kit. The paste and primer are packaged in plastic syringes and plastic bottles, respectively. The device also comes with a mixing dish (dispensing well), disposable applicator, and cement mixing tip.

The paste is dispensed in an automix syringe and is available in various shades (universal, clear, brown and white-opaque). The primer kit components consist of ESTELINK (bond A/bond B) and Tokuyama Universal Primer (A/B). The ESTELINK bond promotes the adhesion of the paste to the tooth structure. The Tokuyama Universal Primer enhances the adhesion of the paste to prosthetic materials.

The ESTECCEM device does not come sterilized and is not intended to be sterilized prior to use.

807.92(a)(5): Intended Use

The ESTECCEM device is an adhesive resin cement for the cementation of crowns, bridges, inlays, and onlays made of glass/oxide ceramics (porcelain, zirconia and alumina), metals/alloys (precious and non-precious) and resin materials including inorganic filler (composite materials). The ESTECCEM device is indicated for:

- Repair of fractured porcelain fused to metal crowns and all ceramic restorations
- Cementation of veneers
- Cementation of adhesion bridges
- Cementation of metal or resin cores, metal or glass-fiber posts

807.92(a)(6): Technological Characteristics

The ESTECCEM device has the same basic technological characteristics in terms of design, material, and chemical composition as the predicate devices identified above. The ESTECCEM device does not have an energy source. Although the chemical compositions are not identical, the material properties, principles of operation, and performance characteristics of the ESTECCEM device are comparable to the selected predicates, as demonstrated in part by the non-clinical performance bench testing described below.

807.92(b)(1): Non-clinical Testing

Non-clinical testing of the physical properties of the ESTECCEM device were conducted, including film thickness, working time, setting time, flexural strength, water sorption, color stability, radio-opacity, tensile strength, and biocompatibility testing in accordance with ISO 4049:2009, ISO 7405:2008, and ISO 10993-1:2009, ISO 10993-3 (genotoxicity), ISO 10993-5 (cytotoxicity), ISO 10993-10 (sensitization and irritation), and ISO 10993-11 (systemic toxicity).

807.92(b)(2): Clinical Testing

There were no clinical tests performed for the ESTECCEM device.

807.92(b)(3): Conclusions from Testing

Based on the non-clinical testing conducted of the physical properties of the ESTECCEM device and the biocompatibility testing as described above, it is concluded that the ESTECCEM device is as safe, as effective, and performs as well as or better than the predicate devices.

Predicate devices

Device name	ESTECEM	BISTITE II DC	CLEARFIL ESTHETIC CEMENT & DC BOND ¹⁾	MULTILINK AUTOMIX	DUOLINK II ²⁾
Manufacturer	Tokuyama Dental Corporation	Tokuyama Dental Corporation	Kuraray Noritake Dental Inc.	Ivoclar Vivadent AG	Bisco, Inc.
510(K) no.	pending	K011685	K062410	K123397	K101787
Licence no. (Health Canada)	pending	60061	73128	79221	30968
Device classification name	Cement, Dental	Cement, Dental	Cement, Dental	Material, Tooth Shade, Resin	Cement, Dental
Product code	EMA	EMA	EMA	EBF	EMA
Indication for use	<ol style="list-style-type: none"> 1. Cementation of crowns, bridges, inlays, and onlays made of glass/oxide ceramics (porcelain, zirconia and alumina), metals/alloys (precious and non-precious) and resin materials including inorganic filler (composite materials) 2. Repair of fractured porcelain fused to metal crowns and all ceramic restorations 3. Cementation of veneers 4. Cementation of adhesion bridges 5. Cementation of metal or resin cores, metal or glass-fiber posts 	For use as dental cement in various applications, including luting, repair of fractured porcelains or crown and bridge resins, cementation of adhesive bridge prostheses and CR core posts	<ol style="list-style-type: none"> 1. Cementation of crowns, bridges, inlays and onlays made of porcelain, ceramic, hybrid ceramics, composite resin or metal 2. Cementation of veneers 3. Cementation of adhesion bridges 4. Cementation of metal cores, resin cores, metal posts or glass-fiber posts 	Multilink Automix is used for the permanent cementation of indirect restorations where a strong bond is desired: Inlays, onlays, crowns, bridges and root posts made of: <ul style="list-style-type: none"> – Metal and metal ceramics – All-ceramics, in particular opaque zirconium oxide ceramics – Composites and fibre-reinforced composites 	<ol style="list-style-type: none"> 1. All indirect restorations (i.e. crowns, bridges, inlay, and onlays fabricated from metal composite, porcelain, ceramic, zirconia, alumina, etc.) 2. All endodontic posts (i.e. fiber, composite and metal) 3. All abutments (i.e. screws)
Components	<ul style="list-style-type: none"> - Paste (A and B) Primer Kit - Bond A/Bond B) and Tokuyama Universal Primer (A/B) 	<ul style="list-style-type: none"> - Bistite II Paste (A and B) - Primer 1 A - Primer 1 B - Primer 2 - Metaltite - Tokuso Ceramic Primer A - Tokuso Ceramic Primer B - Air Barrier 	<ul style="list-style-type: none"> - Paste (A and B) - Try In Paste 	<ul style="list-style-type: none"> - Multilink Automix (Base and Catalyst) - Multilink Primer A - Multilink Primer B 	<ul style="list-style-type: none"> - Duo-Link Universal (Base and Catalyst)
Principle of operation	Dental cement that is cured by chemical and/or photo polymerization reaction. (Dual-cure)	Dental cement that is cured by chemical and/or photo polymerization reaction. (Dual-cure)	Dental cement that is cured by chemical and/or photo polymerization reaction. (Dual-cure)	Dental cement that is cured by chemical and/or photo polymerization reaction. (Dual-cure)	Dental cement that is cured by chemical and/or photo polymerization reaction. (Dual-cure)

1) This device is presumably marketed with the proprietary name as “CLEARFIL ESTHETIC CEMENT EX.”

2) This device is presumably marketed with the proprietary name as “DUO-LINK UNIVERSAL.”