



Food and Drug Administration
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February 25, 2016

Essential Dental Systems, Inc.
Mr. Jeffrey Wan
Research and Development Manager
89 Leuning Street, Suite 8
South Hackensack, New Jersey 07606

Re: K152691
Trade/Device Name: EDS Universal Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: January 25, 2016
Received: January 27, 2016

Dear Mr. Wan:

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" (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,



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

Section 4 - Indications for Use

510(k) Number (if known): K152691

Device Name: EDS Universal Cement

Indications for Use:

- Final cementation of ceramic, composite, or metal inlays, onlays, crowns, bridges, posts, and screws.
- Final cementation of ceramic, composite, or metal restorations on implant abutments.
- Permanent cementation of ceramic or composite veneers.

Prescription Use X
(Per 21 CFR 801 Subpart D)

OR

Over the Counter Use _____
(Per 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5 - 510(k) Summary

1. Submitter's Identification:

Essential Dental Systems
89 Leuning Street
South Hackensack, NJ 07606

Date Summary Prepared: February 18, 2016

Contact: Mr. Jeffrey Wan
Contact Email: jwan@edsdental.com
Contact Phone #: 201-487-9090 ext. 118
Contact Fax #: 201-487-5120

2. Name of the Device:

Trade name: EDS Universal Cement
Common name: Dental cement other than zinc oxide-eugenol
Classification name: Dental Cement
CFR Number: 872.3275
Device class: Class II
Product Code: EMA

3. Predicate Device Information:

Primary predicate: Unicem HM, 3M ESPE AG, K100908
Reference predicate: CALIBRA™ CEMENT, Dentsply International, K040906

4. Device Description:

EDS Universal Cement is an automix, dual-curing, self-adhesive resin cement. This multi-purpose device can be used to affix a variety of ceramic, composite, or metal restorations without the aid of an etchant or bonding agent. The device is comprised of two pastes (base and catalyst) that contain dimethacrylate resins, inorganic filler particles (60% by wt), and a photoinitiator system. The mixing ratio is roughly 1 part base to 1 part catalyst. The device is packaged in a 5 mL dual-barreled syringe and comes in three shades: translucent (white), opaque (white), and A2 (tooth colored).

EDS Universal Cement provides a bond between tooth surfaces (dentin and enamel) and ceramic, composite, and metal restorations. The device provides radiopacity and is resistant to mechanical stress and water damage.

EDS Universal Cement is provided non-sterile and has a shelf-life of two years.

5. Indications for Use:

- Final cementation of ceramic, composite, or metal inlays, onlays, crowns, bridges, posts, and screws.
- Final cementation of ceramic, composite, or metal restorations on implant abutments.
- Permanent cementation of ceramic or composite veneers.

6. Comparison to Predicate Devices:

A comparison of EDS Universal Cement and the predicate devices indicates the following similarities and differences to the devices which received 510(k) clearance:

	Proposed Device	Primary Predicate	Reference Predicate
510(k)	To be assigned	K100908	K040906
Device Name	EDS Universal Cement	Unicem HM	Calibra™ Cement
Manufacturer	Essential Dental Systems	3M ESPE	Dentsply International
Indications for Use	<ul style="list-style-type: none"> - Final cementation of ceramic, composite, or metal inlays, onlays, crowns, bridges, posts, and screws. - Final cementation of ceramic, composite, or metal restorations on implant abutments. - Permanent cementation of ceramic or composite veneers. 	<ul style="list-style-type: none"> - Final cementation of ceramic, composite or metal inlays, onlays, crowns, bridges, 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis). - Final cementation of post and screws. - Final cementation of ceramic, composite or metal restorations on implant abutments. - Cementation of abutments made of Lava™ zirconium oxide ceramic. 	<ul style="list-style-type: none"> - Adhesive cementation of ceramic, porcelain, or composite inlays/onlays, veneers, or crowns. - Adhesive cementation of all metal crowns, bridges, inlays/onlays including precious, semi-precious, and non-precious metals. - Adhesive cementation of PFM (porcelain fused to metal) crowns and bridges. - Adhesive cementation of prefabricated and cast posts. - Adhesive cementation of resin-bonded retainer bridges (Maryland bridges)
Composition	Methacrylate resins and inorganic filler	Methacrylate resins and inorganic filler	Methacrylate resins and inorganic filler
Shades	Translucent, opaque (white), A2	Translucent, A2, A3 opaque	Translucent, light, medium, opaque, bleach

EDS Universal Cement is similar to the predicate devices Unicem HM and Calibra™ in that they are all automix, self-adhesive, dual-curing resin cements intended for ceramic, composite, or metal restorations. All devices are paste/paste systems with similar filler ratios. EDS Universal Cement is also similar to Calibra™ in that they are intended for the cementation of veneers.

EDS Universal Cement is different from the predicate devices in the number and type of shades available. EDS Universal Cement is also different from Unicem HM in that Unicem HM does not have an intended use for the cementation of veneers. The subject device and primary predicate have slightly different Indications for Use language. However, the difference in language does not change the intended use or substantial equivalence.

All of the components found in the predicate devices have been used in legally marketed devices. We believe that prior use of components in legally marketed devices, the performance and biocompatibility data provided support the substantial equivalence of EDS Universal Cement for the indicated uses.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as Follows:**

Testing of biocompatibility, physical properties, and adhesion to dentin and ceramic surfaces were conducted to determine equivalence of EDS Universal Cement to the predicate device Unicem HM.

Equivalence in safety to the predicate device was demonstrated by conducting four biocompatibility tests:

- Cytotoxicity testing according to ISO 10993-5
- Sensitization testing according to ISO 10993-10
- Implantation testing according to ISO 10993-6
- Genotoxicity testing according to ISO 10993-3

Equivalence in performance to the predicate device was demonstrated by conducting comparative shear bond strength testing to natural tooth structure and various crown materials.

Samples of the subject and predicate devices were cured onto dentin, enamel, zirconia, and lithium disilicate surfaces. Shear loading was applied at the cement-surface interface until debonding occurred.

Fluoride release testing was conducted on the subject device to determine its fluoride release profile.

Samples of the subject device were immersed in distilled water. The fluoride concentration was measured at 1, 3, and 7 days. No fluoride was released over a 7 day period.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

EDS Universal Cement is substantially equivalent to the cleared and marketed predicate device Unicem HM.