November 5, 2019

3M Deutschland GMBH
% Prithul Bom
Official Correspondent
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K192992
Trade/Device Name: Suglue 3
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental cement
Regulatory Class: Class II
Product Code: EMA
Dated: October 24, 2019
Received: October 25, 2019

Dear Prithul Bom:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K192992

Device Name
Suglue 3

Indications for Use *(Describe)*

Use of Suglue 3 in Adhesive Mode with ADH19
•Final cementation of all-ceramic or metal Maryland bridges and 3-unit inlay/onlay bridges
•Final cementation of all-ceramic or composite veneers and occlusal veneers (tabletops)

Use of Suglue 3 in Adhesive Mode with ADH19 or in Self-Adhesive Mode
•Final cementation of all-ceramic, composite, or metal inlays and onlays, crowns, and bridges
•Final cementation of posts made of ceramic, glass fiber-reinforced composite or metal, and screws
•Final cementation of all-ceramic, composite, or metal restorations on implant abutments

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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**FORM FDA 3881 (7/17)** Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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**510(k) Summary** K192992

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Establishment Registration Number: 9611385

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Date: ..... September 6, 2019

Trade Name: ..... Suglue 3

Common Name: ..... Resin cement

Classification Name:..... Resin cement
..... (21 CFR 872.3275, product code EMA)

Device Class: ..... Class II

Primary Predicate Device ..... RelyX Unicem 2 Automix (K100756)
Reference Predicate Device ..... RelyX Ultimate (K110508)

Description of Device

Suglue 3 is a dual-curing universal cement that is used for both adhesive and self-adhesive cementation of indirect restorations and posts, whereas RelyX Unicem 2 Automix is a self-adhesive cement and RelyX Ultimate is an adhesive cement. New redox initiator system provides improved bond strength to tooth structure, especially dentin. Changed characteristics allow easier excess removal. Increased radioopacity facilitates clinicians to see the Suglue 3 in radiographs as well as tooth like fluorescence for an esthetic appearance, especially in the anterior region. Suglue 3 is used in combination with ADH19 (dental adhesive, product of 3M Deutschland GmbH) for adhesive cementation. ADH19 adhesive is self-etching. Optionally, the adhesive strength can be enhanced further through additional etching of the tooth structure with Scotchbond Universal Etchant (product of 3M Deutschland GmbH). Standard cases as well as post cementations can be solved securely and efficiently when Suglue 3 is used in self-adhesive mode.

Applicable Standards for Product Tests

No ISO standard for performance testing applies to the resin cement Suglue 3. However, some *in vitro* data were obtained using methods described in ISO standards for other cement classes (e.g. ISO 4049:2009, ISO 9917-1:2008).

Indications for Use of Suglue 3

Use of Suglue 3 in Adhesive Mode with ADH19

- Final cementation of all-ceramic or metal Maryland bridges and 3-unit inlay/onlay bridges
- Final cementation of all-ceramic or composite veneers and occlusal veneers (tabletops)

Use of Suglue 3 in Adhesive Mode with ADH19 or in Self-Adhesive Mode

- Final cementation of all-ceramic, composite, or metal inlays and onlays, crowns, and bridges
- Final cementation of posts made of ceramic, glass fiber-reinforced composite or metal, and screws
- Final cementation of all-ceramic, composite, or metal restorations on implant abutments

Comparison

Suglue 3 was compared to RelyX Unicem 2 Automix and RelyX Ultimate regarding indications for use, intended use, composition, technology, and physical and mechanical properties. The tables below summarize the indications and technology of Suglue 3 and predicate devices:

| **Device** | **Suglue 3** | **RelyX Unicem 2 Automix (K100756)** | **RelyX Ultimate (K110508)** |
|---|---|---|---|
| **Intended Use** | | | |
| Dental luting agent for cementation of indirect restorations | X | X | X |
| **Indications for Use** | | | |
| | *Use of Suglue 3 in Adhesive Mode with ADH19* | | *Using Scotchbond Universal adhesive* |
| Final cementation of all-ceramic or metal Maryland bridges and 3-unit inlay/onlay bridges | X | X | X |
| Final cementation of all-ceramic or composite veneers and occlusal veneers (tabletops) | X | - | X |
| | *Use of Suglue 3 in Adhesive Mode with ADH19 or in Self-Adhesive Mode* | | *Using Scotchbond Universal adhesive* |

| | | | |
|---|---|---|---|
| Final cementation of all-ceramic, composite, or metal inlays and onlays, crowns, and bridges | X | X | X |
| Final cementation of posts made of ceramic, glass fiber-reinforced composite or metal, and screws | X | X | X |
| Final cementation of all-ceramic, composite, or metal restorations on implant abutments | X | X | X |

**Table** Comparison of indications

| **Device** | **Suglue 3** | **RelyX Unicem 2 Automix (K100756)** | **RelyX Ultimate (K110508)** |
|---|---|---|---|
| **Technology** | | | |
| Dual-cure resin cement | X | X | X |
| Consists of base paste and catalyst paste | X | X | X |
| Composition: Monomers, fillers, Initiators, stabilizers, pigments | X | X | X |
| Supplied in Automix syringe and applied via mixing tips | X | X | X |

**Table** Comparison of technology

Suglue 3, RelyX Unicem 2 Automix, and RelyX Ultimate are dental dual-cure resin cements consist of two components (base paste and catalyst paste) containing monomers, fillers, initiators, stabilizers, and pigments. Base paste and catalyst paste of the cements are supplied in automix syringes and applied via mixing tips. 3M Deutschland GmbH is providing information to FDA about the composition of Suglue 3 and compared this to the predicate devices.

*In vitro* testing was conducted to show the performance of Suglue 3 and compared to the predicate devices RelyX Unicem 2 Automix and RelyX Ultimare regarding excess removal forces, pull-out bond strength to endodontic post, shear bond strength to tooth structure (dentin and enamel), glass ceramic (feldspathic and lithium disilicate ceramics), zirconia, metals (gold, remanium, and titanium), and composites. Tests on Suglue 3, RelyX Unicem 2 Automix, and RelyX Ultimate were performed for film thickness, working time, setting time, flexural strength, water sorption, solubility, shade, color stability, radioopacity, and compressive strength. The results of Suglue 3 are comparable to RelyX Unicem 2 Automix, and RelyX Ultimate. In summary, 3M Deutschland GmbH concludes that Suglue 3 is substantially equivalent to the predicate devices regarding performance and physical and mechanical properties.

Biocompatibility

The biocompatibility assessment for the product was conducted in accordance with the following guidance:

| Guidance | Edition | Title |
|---|---|---|
| US FDA Docket Number FDA-2013-D-0350. CDRH Document Number 1811 | June 16, 2016 | Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process - Guidance for Industry and Food and Drug Administration Staff |
| ISO 10993-1 | 2018 | Evaluation and testing within a risk management process |
| ISO 10993-3 | 2014 | Tests for genotoxicity, carcinogenicity and reproductive toxicity |
| ISO 10993-5 | 2009 | Tests for *in vitro* cytotoxicity |
| ISO 10993-6 | 2016 | Tests for local effects after implantation |
| ISO 10993-10 | 2010 | Tests for irritation and skin sensitization |
| ISO 10993-11 | 2017 | Tests for systemic toxicity |
| ISO 10993-12 | 2012 | Sample preparation and reference materials |
| ISO 10993-18 | 2005 | Chemical characterization of materials |
| ISO/TR 10993-22 | 2017 | Guidance on nanomaterials |
| ISO 7405 | 2018 | Evaluation of biocompatibility of medical devices used in dentistry |

**Table** Guidances for biocompatibility assessment

The biocompatibility of Suglue 3 has been assessed by a board-certified toxicologist according to recommendations in FDA guidance and internationally recognized standards for medical and dental devices. The conclusion of the assessment is that Suglue 3 is safe for its intended use.

Conclusion

Comparisons of the intended use, indications for use, composition, technology, and physical and mechanical properties showed that Suglue 3 does not raise any new questions about safety and effectiveness and is substantially equivalent to the predicate devices.