October 31, 2019

3M Deutschland GmbH
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K192961
Trade/Device Name: Adh19
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin tooth bonding agent
Regulatory Class: Class II
Product Code: KLE
Dated: October 21, 2019
Received: October 22, 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 Assistant 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)*
K192961

Device Name
ADH19

Indications for Use *(Describe)*

Direct Indications:

•Bonding for all methacrylate-based light-, dual-, and self-cure composite or compomer filling materials
•Root surface desensitization
•Bonding of methacrylate-based fissure sealants
•Protective varnish for glass ionomer fillings
•Repair of composite and compomer fillings
•Sealing of cavities prior to placement of amalgam restorations

Indirect Indications:

•Cementation of indirect restorations in combination with Suglue 3 and other resin cements (follow applicable Instructions for Use)
•Bonding for all methacrylate-based light-, self-, and dual-cure core build-up materials and cements
•Cementation of veneers when combined with RelyX Veneer Cement
•Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer
•Sealing of cavities and preparation of tooth stumps prior to temporary cementation of indirect restorations

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.

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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

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Date: ..... August 21, 2019

Trade Name: ADH19

Common Name: ..... Adhesive

Classification Name:..... Resin Tooth Bonding Agent
..... (21 CFR 872.3200, product code KLE)

Device Class: ..... Class II

Predicate Devices ..... Scotchbond Universal (K110302)

Description of Device

ADH19 is a one-component dental adhesive that is based on the chemistry of Scotchbond Universal (by 3M Deutschland GmbH, K110302, cleared as ADHESIVE EXL-759). It can be used in a self-etch mode, selective enamel etch mode or in a total-etch mode for both direct and indirect dental restorative procedures. It is intended to bond methacrylate-based restorative, cement and sealant materials to dentin, enamel, glass ionomer and various indirect restorative substrates (metals, glass ceramics, alumina and zirconia). The primary use will be with light-cured materials, however it will have the capability to also bond self- or dual-cure composite and cement materials. In contrast to Scotchbond Universal, no separate Dual Cure Activator will be necessary in this case.

Applicable Standards for Product Tests

- ISO 29022: 2013: Dentistry - Adhesive - Notched-edge sheer bond strength test

Indications for ADH19

Direct Indications:

- Bonding for all methacrylate-based light-, dual-, and self-cure composite or compomer filling materials
- Root surface desensitization
- Bonding of methacrylate-based fissure sealants
- Protective varnish for glass ionomer fillings
- Repair of composite and compomer fillings
- Sealing of cavities prior to placement of amalgam restorations

Indirect Indications:

- Cementation of indirect restorations in combination with Suglue 3 and other resin cements (follow applicable Instructions for Use)
- Bonding for all methacrylate-based light-, self-, and dual-cure core build-up materials and cements
- Cementation of veneers when combined with RelyX Veneer Cement
- Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer
- Sealing of cavities and preparation of tooth stumps prior to temporary cementation of indirect restorations

Comparison

ADH19 was compared to Scotchbond Universal regarding indications for use, intended use, composition, technology and physical and mechanical properties. The tables below summarize the indications and technology of ADH19 and predicate devices:

Indications Comparison	**ADH19**	**Scotchbond Universal (K110302)**
Indications for Use (from the labeling)		
Bonding for all methacrylate-based light-, dual-, and self-cure composite or compomer filling materials	X	X partly with Dual Cure Activator
Root surface desensitization	X	X
Bonding of methacrylate-based fissure sealants	X	X
Protective varnish for glass ionomer fillings	X	X

Indications Comparison	ADH19	Scotchbond Universal (K110302)
Repair of composite and compomer filling	X	X
Sealing of cavities prior to placement of amalgam restorations	X	X
Cementation of indirect restorations in combination with Suglue 3 for ADH19 or Suglue 10 for Scotchbond Universal and other resin cements (follow applicable Instructions for Use)	X	X partly with Dual Cure Activator
Bonding for all methacrylate-based light-, self-, and dual-cure core build-up materials and cements	X	X partly with Dual Cure Activator
Cementation of veneers when combined with RelyX Veneer Cement	X	X
Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer	X	X
Sealing of cavities and reparation of tooth stumps prior to temporary cementation of indirect restorations	X	X
Intended Use A material primarily intended to be used as a bonding-promoting substance between tooth substance and dental restorations. It may also be used as a dentin sealant and as a bonding agent for repair of restorations.	X	X

Table Comparison of indications

Technology	ADH19	Scotchbond Universal (K110302)
Vial for multiple dosing and the L-Pop delivery device for unit dosed dispensing	X	X
One-component dental adhesive	X	X
Self-etch mode, selective enamel etch mode or in a total-etch mode for both direct and indirect dental restorative procedures	X	X
Need to incorporate a separate ceramic or metal primer	Not required	Not required
No separate Dual Cure Activator required to bond self- or dual-cure composite and cement materials	Not required	Required

Table Comparison to Predicate Technology

ADH19 and Scotchbond Universal are dental adhesive materials containing monomers, fillers, solvents, initiators, silanization agents and stabilizers. 3M Deutschland GmbH is providing

information to the Agency regarding information to FDA about the composition of ADH19 and compared this to the predicate device.

In vitro testing was conducted to show the performance of ADH19 compared to the predicate device Scotchbond Universal regarding shear bond strength to enamel (self-etch & total-etch), to dentin (self-etch & total-etch), to restoration materials titanium, zirconia, NPM alloy, composite, high gold alloy, feldspathic glass ceramic, lithium disilicate, with RelyX Ultimate to enamel and dentin, and with different self cure and dual cure composites to enamel and dentin. The results of ADH19 are comparable to Scotchbond Universal. In summary, 3M Deutschland GmbH concludes that ADH19 is substantially equivalent to the predicate devices regarding performance and physical and mechanical properties.

Biocompatibility

The biocompatibility assessment for the products 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 ADH19 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 ADH19 is safe for its intended use.

Conclusion

Comparisons of the indications for use/intended use, composition, technology, and physical and mechanical properties showed that ADH19 does not raise any new questions about safety and effectiveness and is substantially equivalent to the predicate device.