January 12, 2023

Kerr Corporation
Viviana Lai
Principal Specialist, Regulatory Affairs
1889 W Mission Blvd
Pomona, California 91766

Re: K222830
Trade/Device Name: Rainbow 360
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: October 14, 2022
Received: October 14, 2022

Dear Viviana Lai:

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222830

Device Name
Rainbow 360

Indications for Use *(Describe)*

Direct Applications
• Light-cure, self-cure and dual cure composite and compomer restorations.
• Composite/ceramic/metal repairs.
• Tooth preparation and root surface sealer.
• Cavity sealing for amalgam restorations.
• Light-cured or dual-cured core build-ups.
• Bonding of methacrylate-based fissure sealants.

Indirect Applications
• Cementation of veneers
• Cementation of porcelain, composite, and metal-based restorations
• Cementation of endodontic posts
• Cavity sealing as a pretreatment for indirect restorations.
• Prime metal, ceramic, and composite substrates/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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter Information:

Kerr Corporation
1889 W Mission Blvd
Pomona, CA 91766
USA

Contact Person: Viviana Lai
Telephone Number: (714) 516-7760
Email: Viviana.lai@envistaco.com

Date Prepared: December 21, 2022

Device Name:

Proprietary Name: Rainbow 360
Manufacturer: Kerr Corporation
Common Name: Resin Tooth Bonding Agent
Classification Name: Resin Tooth Bonding Agent
CFR Number: 21 CFR 872.3200
Device Class: II
Product Code: KLE

Predicate Device:

Proprietary Name: ADH19 (K192961)
Manufacturer: 3M Deutschland GmbH
Common Name: Resin Tooth Bonding Agent
Classification Name: Resin Tooth Bonding Agent
CFR Number: 21 CFR 872.3200
Device Class: II
Product Code: KLE

Description of Device:

The subject device, Rainbow 360, is a single-component universal dental adhesive intended for direct and indirect dental restorations. Rainbow 360 is formulated to provide reliable bond strengths with any etch technique, on all common substrates and in combination with any resin cements without auxiliary products (silane or metal primers) even in absence of light. Rainbow 360 is available in bottles for multiple uses and Unidose™ for single use. Rainbow 360 is intended for general population use by a dental professional.

Principle of Operation / Mechanism of Action:

Rainbow 360 contains an acidic component to etch the tooth surface in order to allow the adhesive to mechanically adhere to the prepared tooth surface. The adhesive can be used with light or without light curing prior to application of the restorative material. This allows for the adhesive to mechanically and chemically bond to the applied restorative material. Rainbow 360 is formulated to provide a reliable bond strength, and it's compatible with all etching modes (self-etch, selective etch, and total etch).

Indications for Use:

Direct Applications

- Light-cured, self-cured and dual-cured composite and compomer restorations.
- Composite/ceramic/metal repairs.
- Tooth preparation and root surface sealer.
- Cavity sealing for amalgam restorations.
- Light-cured or dual-cured core build-ups.
- Bonding of methacrylate-based fissure sealants.

Indirect Applications

- Cementation of veneers
- Cementation of porcelain, composite, and metal-based restorations
- Cementation of endodontic posts
- Cavity sealing as a pretreatment for indirect restorations.
- Prime metal, ceramic, and composite substrates/restorations.

Description of Substantial Equivalence:

Table 5-1 below compares the Rainbow 360 to the Predicate device (Adh19 aka 3M™ Scotchbond™ Universal Plus (K192961)) with respect to intended use, technological characteristics, and performance testing.

Details of the Similarities between the Subject and Predicate Devices:

Rainbow 360 and the predicate device have the same intended use and similar indication for use.

The delivery system is identical between both devices as a one-component dental adhesive.

The technological principle for both the subject and predicate devices is to bond methacrylate-based restorative materials, cement and sealants to dentin, enamel, and various indirect restoratives with all etching techniques - total-etch, self-etch and selective etch used for direct and indirect indications.

Details of the differences between the Subject and Predicate Devices:

There are no major differences between the subject device (Rainbow 360) and the predicate device (Adh19, K192961), however, there are some minor differences between the two devices.

There is an additional indication for use in the predicate device for protective varnish for glass ionomer fillings in direct application. This particular indication for use is not applied to the subject device, Rainbow 360. The chemical composition is slightly different between the two devices as well as the configuration.

Conclusion:

Based on a comparison of intended use, indications for use, technological characteristics, the principle of operation, features, and performance data, the Rainbow 360 is deemed to be substantially equivalent to the Predicate Device as it satisfies all criteria of substantial equivalence and does not raise new concerns regarding substantial equivalence: Indications for Use, Technological Characteristics, and Performance Data. The new device does not introduce a fundamentally new scientific technology and the nonclinical tests demonstrate that the device is substantially equivalent.

Table 5-1 Device Comparison Table:

Descriptive Information	**Subject Device** Rainbow 360	**Predicate Device** Adh19 (K192961)	**Comparison**
Pictorial Representation			N/A
Regulation Number	21 CFR 872.3200	21 CFR 872.3200	Same as Predicate
Regulation Title	Resin tooth bonding agent	Resin tooth bonding agent	Same as Predicate
Regulation Class	II	II	Same as Predicate
Product Code	KLE	KLE	Same as Predicate

Descriptive Information	Subject Device Rainbow 360	Predicate Device Adh19 (K192961)	Comparison
Indications for Use	**Direct Applications** • Light-cured, self-cured and dual-cured composite and compomer restorations. • Composite/ceramic/metal repairs. • Tooth preparation and root surface sealer. • Cavity sealing for amalgam restorations. • Light-cured or dual-cured core build-ups. • Bonding of methacrylate-based fissure sealants. **Indirect Applications** • Cementation of veneers • Cementation of porcelain, composite, and metal-based restorations • Cementation of endodontic posts • Cavity sealing as a pretreatment for indirect restorations. • Prime metal, ceramic, and composite substrates / restorations.	**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	Same Indication for Use as Predicate and expressed through a similar choice of words.
Intended Use	Rainbow 360 is a universal bonding agent intended to bond methacrylate-based restorative materials, cements and sealants to dentin, enamel, and various indirect restorative substrates. It can be used in a self-etch mode, selective etch mode or in a total-etch mode for both direct and indirect dental restorative procedures.	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. 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 and it will have the capability to also bond self- or dual-cure composite and cement materials.	Same intended use as Predicate and expressed through a similar choice of words.

Descriptive Information	Subject Device Rainbow 360	Predicate Device Adh19 (K192961)	Comparison
Composition	Phosphoric acid modified methacrylate, monofunctional methacrylate, difunctional methacrylate, acidic methacrylate, water, ethanol, acetone, initiator, stabilizer, and silica filler.	MDP Phosphate Monomer, HEMA, 3M™ Vitrebond™ Copolymer, Filler, Ethanol, water, initiators, silane, and Dimethacrylate resins.	Similar as Predicate
One-component dental adhesive	One-component dental adhesive	One-component dental adhesive	Same as Predicate
Configurations	5ml bottle for multiple uses 0.18 ml Unidose for single use	5ml Vial 0.11 ml Unit Dose	Similar as Predicate
Single Use	Yes	Yes	Same as Predicate
Non-Sterile	Yes	Yes	Same as Predicate
Technological Characteristics			
Workflow/Technique	Self-etch, selective etch, and total etch	Self-etch, selective etch, and total etch	Same as Predicate
Substrate's compatibility	Dentin, enamel, composite, metal, porcelain/ceramic substrates	Dentin, enamel, resin, compomer, metal, ceramic substrates	Same as Predicate
Cements compatibility	Compatible with resin cements	Compatible with resin cements	Same as Predicate
Shelf life	2 years	2 years	Same as Predicate
Performance Testing			
Bond strength test	ISO 29022	ISO 29022	Same as Predicate
Biocompatibility testing	Biocompatible per ISO 10993-1 and ISO 7405	Biocompatible per ISO 10993-1 and ISO 7405	Same as Predicate

Non-Clinical Test Data:

Kerr conducted design verification performance testing to verify, demonstrate and support the claim of substantial equivalence to the predicate device. All test results met their acceptance criteria and support that the Rainbow 360 is appropriately designed for their intended use.

Kerr conducted design verification performance testing according to the FDA recognized/ voluntary consensus standards and guidelines.

- ISO 29022:2013, "Dentistry - Adhesive - Notched-edge sheer bond strength test"
- ASTM D4169:2016, "Standard Practice for Performance Testing of Shipping Containers and Systems"

Biocompatibility

Biocompatibility assessments were conducted in accordance with ISO-10993-1:2018, *"Biological evaluation of medical devices – part 1: Evaluation and testing within a risk management process"*, U.S. Food and Drug Administration (FDA) Guidance Document for the Use of ISO 10993-1 (issued 09/04/2020) guidelines and ISO 7405:2018 *"Dentistry - Evaluation of biocompatibility of medical devices used in dentistry"* as guidance. Kerr performed the biocompatibility testing of the finished product according to the following parts of the ISO 10993 and ISO 7405 standard.

- ISO 7405:2018, "Dentistry - Evaluation of biocompatibility of medical devices used in dentistry"
- ISO 10993-2:2006, "Biological evaluation of medical devices – part 2: Animal welfare requirements"
- ISO 10993-3:2014, "Biological evaluation of medical devices – part 3: Tests for genotoxicity, carcinogenicity and reproductive"
- ISO 10993-5:2009, "Biological evaluation of medical devices – part 5: Tests for in vitro cytotoxicity"
- ISO 10993-6:2016, "Biological evaluation of medical devices – part 6: Tests for local effects after implantation"
- ISO 10993-10:2021, "Biological evaluation of medical devices – part 10: Tests for irritation and delayed-type hypersensitivity"
- ISO 10993-11:2017, "Biological evaluation of medical devices - Part 11: Tests for systemic toxicity"
- ISO 10993-12:2021, "Biological evaluation of medical devices- part 12: Sample preparation and reference materials"
- ISO 10993-23:2021, "Biological evaluation of medical devices – Part 23: Tests for irritation"

In addition to the above testing performed according to the ISO standards, the following internal performance testing was also conducted:

- Shelf-life testing

Clinical Performance Data:

Clinical data is not required to characterize performance and establish substantial equivalence. The non-clinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on this product.

Conclusion as to Substantial Equivalence:

Based on a comparison of intended use, indications, material composition, technological characteristics, principle of operation, features and performance data, the Rainbow 360 is deemed to be substantially equivalent to the predicate device.