May 29, 2019

3M ESPE Dental Products
℅ Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K191122
Trade/Device Name: 3M RelyX Pediatric Resin Modified Glass Ionomer Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental cement
Regulatory Class: Class II
Product Code: EMA
Dated: April 26, 2019
Received: April 29, 2019

Dear Mark Job:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Malvina B Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

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)*

K191122

Device Name

3M™ RelyX™ Pediatric Resin Modified Glass Ionomer Cement

Indications for Use *(Describe)*

Permanent cementation of pediatric crowns:
- Stainless Steel crowns
- Zirconia crowns
- 3M™ Pediatric Esthetic Crowns

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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3. 510(k) Summary

3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144-1000

510(k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter…… 3M ESPE Dental Products
2510 Conway Ave.
St. Paul, MN 55144 USA

Contact person……..…. Lin Ma, Ph. D.
Regulatory Affairs Specialist
Office: (651) 733-4734
Fax: (651) 736-1599
lma@mmm.com

Date Summary was Prepared…… 28 March 2019

Trade Name……... 3M™ RelyX™ Pediatric Resin Modified Glass Ionomer Cement

Common Name(s)…….…. Dental Cement, Resin Modified Glass Ionomer

Recommended Classification…… 21 CFR 872.3275
Dental Cement
Product Code: EMA

Predicate Devices:

Primary Predicate: 3M™ ESPE™ RelyX™ Luting Plus Automix Resin Modified Glass Ionomer Cement (K111185)

Secondary Predicate: GC FujiCEM™ 2 Radiopaque Reinforced Glass Ionomer Luting Cement (K001730)

Description of Device:

3M™ RelyX™ Pediatric Resin Modified Glass Ionomer Cement is a radiopaque, fluoride-releasing, resin-modified glass ionomer luting cement. RelyX Pediatric Cement is intended for the cementation of preformed pediatric crowns made of stainless steel, zirconia, and resin composite material.

RelyX Pediatric Cement consists of a base paste and a catalyst paste packaged in the Automix delivery system for direct delivery in consistent mix ratios. The mixing tip attachment offers convenience over traditional hand mixed cement systems and delivers consistent mix ratios. The cement is available in a white shade. The Automix syringe contains 8.5 g of cement material. The product provides both self-curing and light curing mechanisms which makes it uniquely versatile for the cementation of different restorative materials.

Indications for Use:

Permanent cementation of pediatric crowns:

- Stainless Steel Crowns
- Zirconia Crowns
- 3M™ Pediatric Esthetic Crowns

Technological Characteristics:

Luting cements, including resin modified glass ionomer cements, are widely used to cement crowns for children and adults. Luting cements fill the gap between the crown and prepared tooth; the cured cements provide the mechanical interlock between the crown and the tooth structure. The cured resin modified glass ionomer cements not only provide strong mechanical property but also interfacial adhesion to different materials. These properties ensure the longevity of dental restoration for patients. The unique chemistry of resin modified glass ionomer cements provides strong interfacial adhesion to different materials.

RelyX Pediatric Cement is identical to the predicate device, 3M RelyX Luting Plus Automix, in terms of formulation and delivery. RelyX Pediatric Cement is marketed specifically for use with pediatric crowns of stainless steel or zirconia, with an additional indication to cement the 3M Pediatric Esthetic Crown, which is a resin composite crown.

Bonding between the cement and tooth structure or the restorative material occurs by two mechanisms: mechanical bonding through a self-curing mechanism and chemical bonding through a light-curing mechanism. The cement product performs with both self-curing and light-curing mechanisms.

Self-curing: Two mechanical setting reactions occur through the self-curing mechanism.

- An acid-base reaction between the FAS (fluoroaluminosilicate) glass and methacrylated polycarboxylic acid; and
- A free radical polymerization of the methacrylated copolymer and ethylenically unsaturated monomers/agents.

Light-curing: Through the light curing mechanism, a chemical bond forms in the presence of the photoinitiation system, camphorquinone (CPQ) and 4-(dimethylamino)-phenethyl alcohol (DMAPE); and can enhance the interaction between the cement and restorative material, specifically in the case of resin composite crowns.

The cementation of stainless steel and zirconia crowns is adequately achieved by the self-curing mechanism. In comparison, the cementation of 3M Pediatric Esthetic Crown requires an additional step of light-curing during the self-curing process to enhance the bonding between the cement and the resin composite material. When irradiated by light, the methacrylate functionalities of the resins in conjunction with the photoinitiator system polymerize to form a stronger and quicker bond to the resin composite crown. Therefore, the light cure step enhances an adhesive interaction between RelyX Pediatric Cement and 3M Pediatric Esthetic Crown.

Substantial Equivalence:

Information provided in this 510(k) submission shows that the product is substantially equivalent to the predicate devices, 3M ESPE RelyX™ Luting Plus Automix (K111185) and GC FujiCEM™ 2 Luting Cement (K001730).

	Applicant Device	**Primary Predicate**	**Secondary Predicate**
Trade Name	RelyX™ Pediatric	RelyX™ Luting Plus Automix (K111185)	FujiCEM™ 2 (K001730)
Product Category	Resin Modified Glass Ionomer Luting Cement	Resin Modified Glass Ionomer Luting Cement	Resin Modified Glass Ionomer Luting Cement
Intended Use	Dental Luting Cement	Dental Luting Cement	Dental Luting Cement
Indications for Use	Permanent cementation of pediatric crowns: • Stainless Steel crowns • Zirconia crowns • 3M™ Pediatric Esthetic Crowns	RelyX Luting Plus Automix is indicated for Luting: • Luting porcelain fused to metal crowns and bridges to tooth structure, amalgam, composite or glass ionomer core build ups;	1. Cementation of metal-based inlays, onlays, crowns and bridges 2. Cementation of **resin** inlays, onlays, **crowns** and bridges 3. Cementation of all ceramic inlays 4. Cementation of high strength (e. g.

	Applicant Device	Primary Predicate	Secondary Predicate
Trade Name	RelyX™ Pediatric	RelyX™ Luting Plus Automix (K111185)	FujiCEM™ 2 (K001730)
		• Luting **metal** inlays, onlays or **crowns**; • Luting pre-fabricated and cast post cementation; • Luting orthodontic appliances; • Luting **crowns** made with all-alumina or all **zirconia** cores such as Procera® AllCeram	zirconia based, lithium disilicate, etc.) all ceramic inlays, onlyas, crowns and bridges 5. Cementation of metal, ceramic and fiber posts
Contra-indication	None	None	1. Pulp capping. 2. In rare cases, the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.
Technological Characteristics and Mode of Action – Self Curing	Glass Ionomer Tooth bonding properties based on 1. An acid-base reaction between fluoroalumino-silicate glass and methacrylated polycarboxylic acid; 2. A free radical polymerization of the methacrylated copolymer and ethylenically unsaturated monomers/agents; 3. The 2 pastes are delivered in a consistent manner through an Automix delivery system.	Glass Ionomer Tooth bonding properties based on 1. An acid-base reaction between fluoroalumino-silicate glass and methacrylated polycarboxylic acid; 2. A free radical polymerization of the methacrylated copolymer and ethylenically unsaturated monomers/agents; 3. The 2 pastes are delivered in a consistent manner through an Automix delivery system	The device is set by acid-base reaction and polymerization after mixing 2 pastes. 1. Acid-base reaction occurs fluoroalumino-silicate glass in Paste A and polyacrylic acid in Paste B. 2. Polymerization of methacrylate monomers is through chemical cure.

	Applicant Device	Primary Predicate	Secondary Predicate
Trade Name	RelyX™ Pediatric	RelyX™ Luting Plus Automix (K111185)	FujiCEM™ 2 (K001730)
Technological Characteristics and Mode of Action – Light Curing	Photoinitiator system with camphorquinone (CPQ) and 4-(dimethylamino)-phenethyl alcohol (DMAPE): • Tack-curing for excess removal, • Light-curing for enhancing the bond strength to 3M Pediatric Esthetic composite crowns	Photoinitiator system with camphorquinone (CPQ) and 4-(dimethylamino)-phenethyl alcohol (DMAPE): • Tack-curing for excess removal	No light curing.

The technological characteristics and mode of action of RelyX Pediatric Cement is identical to the primary predicate device RelyX Luting Plus Automix in terms of fundamental reactions in self-curing and light-curing modes, in spite of its added enhancement to bond to the resin crown in light-curing mode. RelyX Pediatric Cement is also substantially equivalent to the secondary predicate device GC FujiCEM with respect to the characteristics of resin modified glass ionomer cement and fundamental reactions of acid-base reaction and polymerization.

The safety and efficacy of RelyX Pediatric Cement with stainless steel and zirconia crowns remains unchanged from the primary predicate, 3M RelyX Luting Plus Automix. The indication for use of RelyX Pediatric Cement with stainless steel and zirconia crowns is a subset of the indications for use of the primary predicate device. As RelyX Pediatric Cement is identical to the primary predicate device in formulation and delivery system, no new questions of safety and effectiveness are raised with these indications.

The product was also assessed to ISO 10993-1:2018 and it was confirmed that no additional biocompatibility testing was required to support the submission because the formulation of RelyX Pediatric Cement is identical to the predicate device since the clearance its original 510(k) and continues to meet biocompatibility requirements.

Testing was undertaken to substantiate the use of the RelyX Pediatric Cement with the 3M Pediatric Esthetic Crown, the new indication being added when compared to the predicate devices. This 510(k) submission includes data from *in vitro* testing per FDA Guidance "Guidance for Industry and FDA Staff *Dental Cements – Premarket Notification" issued on August 18, 1998* and ISO 9917-2:2017 *Dentistry – Water-based Cements - Part 2: Resin-modified Cements*. To evaluate the performance of RelyX Pediatric Cement with 3M Pediatric Esthetic composite crowns, comparative testing results for the following physical properties were included in this submission:

- Adhesion to dentin and enamel

- Adhesion to 3M Pediatric Esthetic Crown
- Compressive strength
- Flexural strength
- Fluoride release
- Linear expansion
- Radiopacity
- Color Stability for esthetic properties

The results submitted in the 510(k) demonstrated equivalent or superior bonding of the 3M RelyX Pediatric Cement to the 3M Pediatric Esthetic Crown, dentin and enamel as compared to the primary and secondary predicates.

The stability studies conducted with the primary predicate device, RelyX™ Luting Plus Automix are applicable to RelyX Pediatric Cement because they are identical in formulations, packaging, and intended use. The established shelf life for RelyX Pediatric Cement is 24 months at room temperature within a sealed foil pouch.

Conclusion:

3M™ RelyX™ Pediatric Resin Modified Glass Ionomer Cement is substantially equivalent to the primary predicate device 3M RelyX™ Luting Plus Automix in terms of intended use, formulation, biocompatibility, physical properties, technological characteristics, and indications for use to cement stainless steel and zirconia crowns. 3M™ RelyX™ Pediatric Cement with additional light curing step is substantially equivalent to the secondary predicate device GC FujiCEM™ 2 in terms of intended use and the indication for use to cement 3M Pediatric Esthetic Crown, a resin composite crown. Testing has been conducted that demonstrates the 3M™ RelyX™ Pediatric Resin Modified Glass Ionomer Cement performs as intended with the 3M Pediatric Esthetic composite crowns and the new indication for use with the 3M Pediatric Esthetic composite crowns does not raise new questions of safety or effectiveness.