August 30, 2022

SDI Limited
Antonella Kotefski
Regulatory Affairs Manager
3-15 Brunsdon Street
Bayswater, Victoria 3153
AUSTRALIA

Re: K214118
Trade/Device Name: Riva Cem Automix
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: July 29, 2022
Received: August 3, 2022

Dear Antonella Kotefski:

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, 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)*
K214118

Device Name
Riva Cem Automix

Indications for Use *(Describe)*
Permanent cementation of:
1) Porcelain fused to metal (PFM) to crowns and bridges
2) Prefabricated/cast posts
3) Metals to crowns, bridges, inlays & onlays, orthodontic appliances & posts
4) Ceramics (high strength)* to crowns & bridges, inlays & onlays
*E.g. Zirconia, Lithium Disilicate,
5) Ceramics (low strength)* to inlays
*E.g. Feldspathic porcelains, Glass ceramics

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."

1. Submitter Information

Submitter:	SDI Limited 3-15 Brunsdon Street Bayswater, Victoria 3153 Australia
Contact Person:	Quynh Jewell
Position:	Regulatory Affairs Manager
Phone:	+61 3 8727 7111
Email:	Quynh.Jewell@sdi.com.au

Date Prepared:	24 August 2022

2. Device Details

Proprietary Name:	Riva Cem Automix™
Common Name:	Dental Cement, Resin Modified Glass Ionomer
Regulation Name:	Dental Cement
Regulation Number:	21 CFR 872.3275
Product Code:	EMA
Regulatory Class:	II

3. Predicate Device

Permanent cementation for the following:

Primary Predicate Device	**510(k) Device Number**	**Company Name**
RelyX Luting Plus™	K111185	3M ESPE

Secondary Predicate Device	**510(k) Device Number**	**Company Name**
FujiCEM™ 2	K182854	GC Corporation

4. Device Description

Riva Cem Automix™ is a radiopaque, fluoride releasing, resin modified glass ionomer luting cement.

Riva Cem Automix™ is intended for the cementation of crowns, bridges, inlays, onlays, posts (fibre-reinforced), and orthodontic appliances.

Riva Cem Automix™ consists of a base paste and a catalyst paste packaged in the automix delivery system for direct delivery in consistent mix ratios. Riva Cem Automix™ is available in a universal light-yellow shade in a double barrel syringe. The automix tip offers convenience over traditional hand mixed systems.

The product provides both self-cure and tack cure mechanisms which makes it versatile for the cementation of different restorative systems.

5. Indications of Use

Permanent cementation of:

Indicated Material	**Type of Restoration**
Porcelain fused to metal (PFM)	Crowns & bridges
Prefabricated/cast	Posts
Metals	Crown, bridges, inlays & onlays, orthodontic appliances & posts
Ceramics (high strength)1	Crowns & bridges, inlays & onlays
Ceramics (low strength)2	Inlays

[1] High strength ceramics, e.g. Zirconia, Lithium Disilicate.

[2] Low strength ceramics, e.g. Feldspathic Porcelains, Glass Ceramics.

6. Comparison of Technological Characteristics with the Predicate Device

Luting cements, including resin modified glass ionomer cements, are widely used to cement crowns. Luting cements provide the mechanical interlock between the crown and the other types of restorative materials indicated, and the tooth structure.

Riva Cem Automix™ is identical to predicate devices RelyX™ Luting Plus Automix and FujiCEM™ 2 in terms of technology and delivery.

Two mechanisms provide the bonding between the cement and the tooth structure or restorative material through self-curing and light-curing.

Self-curing the luting cement occurs by an acid-base reaction between the two pastes, as well as polymerisation of the methacrylic polymer.

Light curing also provides the chemical reaction of the two pastes by the photoinitiators in the formulation, enhancing the reaction between the cement and the restorative material.

Substantial Equivalence

Information provided in this 510(k) submission shows that Riva Cem Automix**™** is substantially equivalent to the predicate devices 3M ESPE RelyX™ Luting Plus Automix (K111185) and GC FujiCEM™ 2 Luting Cement (K182854). A comparison of the devices is provided below in Table 1.

Table 1 Comparison of Riva Cem Automix™ with the Primary Predicate and Secondary Predicate Devices

	Submitter Device	Primary Predicate Device	Secondary Predicate Device	Differences
Proprietary Name	Riva Cem Automix™ (K214118)	RelyX™ Luting Plus Automix (K111185)	FujiCEM™ 2 (K182854)	Name
Regulation No.	21 CFR 872.3275	21 CFR 872.3275	21 CFR 872.3275	None
Product Code	EMA	EMA	EMA	None
Regulatory Class	II	II	II	None
Rx / OTC	Rx	Rx	Rx	None
Regulation Name	Dental cement	Dental cement	Dental cement	None
Product Category	Resin Modified Glass Ionomer Luting Cement	Resin Modified Glass Ionomer Luting Cement	Resin Modified Glass Ionomer Luting Cement	None
Intended Use	Dental Luting Cement	Dental Luting Cement	Dental Luting Cement	None
Application	Paste-paste	Paste-paste	Paste-paste	None
Curing	Self-cure, tack cure	Self-cure, tack cure	Self-cure	All are similar. Riva Cem Automix™ and RelyX™ Luting Plus have optional tack cure.
Curing Chemistry	Acid-base and polymerisation reactions	Acid-base and polymerisation reactions	Acid-base and polymerisation reactions	None
Indications for Use (IFU)	Permanent cementation of: - Porcelain fused to metal (PFM) to crowns and bridges - Prefabricated/cast posts - Metals to crowns, bridges, inlays & onlays, orthodontic appliances & posts	<u>510k indications:</u> This device is intended for use as a dental cement. RelyX Luting Plus Automix (Lexus-2) is indicated for Luting: - Luting porcelain fused to metal crowns and bridges to tooth	FujiCEM 2 is indicated for: - Cementation of metal-based inlays, onlays, crowns and bridges - Cementation of resin inlays, onlays, crowns and bridges - Cementation of all ceramic inlays - Cementation of high strength (e.g.	Similar – different wording. See below for comparison of each indication.

	Submitter Device	Primary Predicate Device	Secondary Predicate Device	Differences
Proprietary Name	Riva Cem Automix™ (K214118)	RelyX™ Luting Plus Automix (K111185)	FujiCEM™ 2 (K182854)	Name
	- Ceramics (high strength)* to crowns & bridges, inlays & onlays *E.g. Zirconia, Lithium Disilicate, - Ceramics (low strength)* to inlays *E.g. Feldspathic porcelains, Glass ceramics	structure, amalgam, composite or glass ionomer core build ups; - 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 All Ceram	zirconia based, lithium disilicate) ceramic onlays, crowns and bridges - Cementation of metal, ceramic and fiber posts	
Comparison of IFU	Porcelain fused to metal (PMF) to crowns and bridges	510k indications: Luting porcelain fused to metal crowns and bridges to tooth structure, amalgam, composite or glass ionomer core build ups;	Cementation of metal-based inlays, onlays, crowns and bridges	None (PFM and metal-based are the same regarding cementation as both consist of metal).
	Prefabricated/cast posts	N/A	Cementation of resin inlays, onlays, crowns and bridges Cementation of metal, ceramic and fiber posts	None (except for RelyX™ Luting Plus which it is not indicated)
	Metals to crowns, bridges, inlays & onlays, orthodontic appliances & posts	510k indications: Luting metal inlays, onlays or crowns, Luting orthodontic appliances, Luting prefabricated and cast post cementation	Cementation of metal-based inlays, onlays, crowns and bridges	None
	Ceramics (high strength)* to crowns & bridges, inlays & onlays *E.g. Zirconia, Lithium Disilicate	510k indications: Luting crowns made with all-alumina or all zirconia cores such as Procera	Cementation of high strength (e.g. based, lithium disilicate) ceramic onlays, crowns and bridges	None

	Submitter Device	Primary Predicate Device	Secondary Predicate Device	Differences
Proprietary Name	Riva Cem Automix™ (K214118)	RelyX™ Luting Plus Automix (K111185)	FujiCEM™ 2 (K182854)	Name
		All Ceram		
	Ceramics (low strength)* - Inlays *E.g. Feldspathic porcelains, Glass ceramics	N/A	Cementation of all ceramic inlays	None (except for RelyX™ Luting Plus which it is not indicated)
Light Curing Specification Comparison	The parameters for tack curing are: 1. Use a light curing device • Wavelength: 440-480 nm • Intensity: 1500 mW/cm^2 [+5% / - 15%] 2. Apply for 5 seconds per surface	The parameters for tack curing are: 1. Use a light curing device: • Wavelength: 430-480 nm • Intensity: 1470 mW/cm^2 [-10% / +20%] 2. Apply for 5 seconds per surface.	N/A	Minor differences
Contra-indications	1. Pulp capping 2. Product may cause skin irritations to some people. In such cases, discontinue use and seek medical attention. Any persons having known resin allergies should immediately discontinue use	This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of the product in patients with known acrylate allergies.	1. Pulp capping. 2. Avoid use of this product in patients with known allergies to glass ionomer cement, methacrylate monomer or methacrylate polymer	None (except for RelyX™ Luting Plus which contraindication for pulp capping is not specified)
Technological Characteristics & Mode of Action	A two-component paste/paste system based on: 1.An acid-base reaction between fluoroalumino-silicate glass in and polyacrylic acid copolymer. 2. Polymerization of methacrylate monomers is through chemical cure or light cure. 3. Photoinitiator system: • Tack-curing for excess removal	A two-component paste/paste 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, through chemical	A two-component paste/paste system. The device is set by acid-base reaction and polymerization after mixing 2 pastes. 1. Acid-base reaction occurs between fluoroaluminosilicate glass in Paste A and polyacrylic acid in Paste B. 2. Polymerization of methacrylate monomers is through chemical cure.	None. Devices are paste/paste systems which form an acid-base reaction and polymerisation of methacrylate component. Riva Cem Automix™ and RelyX™ Luting Plus offer a tack

	Submitter Device	Primary Predicate Device	Secondary Predicate Device	Differences
Proprietary Name	Riva Cem Automix™ (K214118)	RelyX™ Luting Plus Automix (K111185)	FujiCEM™ 2 (K182854)	Name
	The 2 pastes are delivered in a consistent manner through an Automix syringe delivery system.	cure or light cure; 3. Photoinitiator system with camphorquinone (CPQ) and 4-(dimethylamino)- phenethyl alcohol (DMAPE): • Tack-curing for excess removal The 2 pastes are delivered in a consistent manner through an automix delivery system		cure and contain photoinitiators.

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Bench testing

The following in-vitro bench tests were performed on Riva Cem Automix™ as per ISO 9917-2 2017 – "Dental water-based cements - Part 2: Resin-modified cements" (Section 5), ISO 29022 - "Dentistry - Adhesive - Notched-edge sheer bond strength test", ISO/TS 11405 – "Dentistry - Testing of adhesion to tooth structure" and an in-house method to verify physical properties and performance in support of substantial equivalence:

- Working time
- Setting time
- Film thickness
- Flexural strength
- Radio-opacity
- Shear Bond strength
- Fluoride release

The performance of Riva Cem Automix™ satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence.

Biocompatibility testing

Biocompatibility testing was conducted according to ISO 10993-1 - *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, and ISO 7405– *Dentistry – Evaluation of biocompatibility of medical devices used in dentistry.*

The results of the biocompatibility testing and composition analysis conducted relating to the subject device Riva Cem Automix™ support its substantial equivalence.

Clinical Performance Data

No data from human clinical studies has been included to support the substantial equivalence of Riva Cem Automix™.

Electrical safety and electromagnetic compatibility (EMC)

This section does not apply.

Software verification and validation testing

This section does not apply.

Mechanical and acoustic testing

This section does not apply.

Animal studies

This section does not apply.

Clinical studies

No data from human clinical studies has been included to support the substantial equivalence of Riva Cem Automix™.

8. Conclusion Regarding Substantial Equivalence

Riva Cem AutomixTM has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the primary predicate RelyX Luting Plus and secondary predicate FujiCEM 2. Test data to verify physical properties and the performance of Riva Cem AutomixTM has been provided including working time, setting time, film thickness, flexural strength and radio-opacity on various substrates. The results of the testing, combined with the design and intended use comparison with both predicate devices, RelyX Luting Plus and FujiCEM 2, support substantial equivalence.