November 13, 2020

Doxa Dental AB
Anna-Lisa Tiensuu
Regulatory Affairs Director
Axel Johanssons Gata 4-6
Uppsala, 75450
SWEDEN

Re: K201937
Trade/Device Name: Ceramir® Restore QuikCap
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: August 13, 2020
Received: August 17, 2020

Dear Anna-Lisa Tiensuu:

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 “Nandu” Nandkumar, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201937

Device Name
Ceramir® Restore QuikCap

Indications for Use *(Describe)*
- Non-load bearing Class I and II restorations
- Deciduous teeth restorations
- Geriatric restorations
- Intermediate restorative and base material for Class I and II cavities using the sandwich technique
- Cervical (Class V) restorations
- Core build ups
- Temporary fillings
- Dentin replacement

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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5 510(k) Summary
K201937

5.1 Submitter information

Submitted by: Doxa Dental AB
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Contact: Anna-Lisa Tiensuu
Phone: +46 70 394 42 99
e-mail: anna-lisa.tiensuu@doxa.se

Date Prepared: November 12, 2020

5.2 Device Name

Proprietary name	Ceramir® Restore QuikCap
Common name:	Bioceramic restorative material
Classification name:	Dental Cement
Device Classification:	Class II, 872.3275
Product code:	EMA

5.3 Predicate device

Product	510(k) No	Code	Predicate / Reference Device
Riva Self Cure	K030516	EMA	Primary Predicate Device
Ceramir Crown & Bridge	K113040	EMA	Reference Device

5.4 Intended Use

Ceramir® Restore QuikCap is a self-curing bioceramic restorative material of glass ionomer type.

5.5 Indications for Use

- Non-load bearing Class I and II restorations
- Deciduous teeth restorations
- Geriatric restorations
- Intermediate restorative and base material for Class I and II cavities using the sandwich technique
- Cervical (Class V) restorations
- Core build ups
- Temporary fillings
- Dentin replacement

5.6 Device Description

Ceramir Restore QuikCap is a self-curing bioceramic restorative material of glass ionomer type. It is a hybrid between a glass ionomer cement and a ceramic cement based on calcium aluminate. The material is radiopaque.

Ceramir Restore QuikCap contains a ceramic powder and a liquid, separated in different compartments, in a plastic capsule.

The capsule is activated just before use, allowing the powder and liquid to blend in the capsule. The content is mixed by using a high-frequency oscillating or rotating capsule mixer.

A capsule applicator, “Ceramir Applicator 2”, is needed to extrude the mixed material into the tooth cavity.

The applied cement is formed using conventional tooth filling techniques. After setting, the material is ready for finishing and dry polishing.

The cement is available in shade A2 and is designated opaque (Vita shade guide).

5.7 Technological characteristics and performance data

Parameter	Subject device Ceramir Restore QuikCap	Primary Predicate device Riva Self Cure (K030516)	Comparison
Intended use	Ceramir Restore® QuikCap is a self-curing bioceramic restorative material of glass ionomer type	Riva Self Cure is a self-curing conventional glass ionomer restorative material	SE
Indications for use	• Non-load bearing Class I and II restorations • Deciduous teeth restorations • Geriatric restorations • Intermediate restorative and base material for Class I and II cavities using the sandwich technique • Cervical (Class V) restorations • Core build ups • Temporary fillings • Dentin replacement	• Non stress bearing Class I and II restorations • Deciduous teeth restorations • Geriatric restorations • Intermediate restorative and base material for Class I and II cavities using the sandwich technique • Cervical (Class V) restorations • Core build ups • Temporary fillings • Dentine replacement • Restorative in the field using the ART technique	SE Since the indications of Ceramir Restore QuikCap is a subset of the cleared indications for Riva Self Cure, the difference will not affect safety and effectiveness of Ceramir Restore QuikCap.
Type of Mixing	Mixed in a capsule supplied by SDI LTD.	Mixed in a capsule supplied by SDI LTD.	SE
Powder to liquid ratio	3.0 g/g	3.2 g/g *	SE

Chemical composition	Glass ionomer/calcium aluminate	Glass ionomer	SE The differences in chemical composition do not raise any new questions of safety or effectiveness as evaluated by performance testing and biological evaluation.
Compressive strength at 24 hours	189 MPa Conforms to ISO 9917-1	171 MPa Conforms to ISO 9917-1**	SE
Radio-opacity	Radiopaque (2.0 mm Al) Conforms to ISO 9917-1	Radiopaque (2.5 mm Al) Conforms to ISO 9917-1**	SE
Maximum solubility and disintegration (Acid erosion)	0.04 mm Conforms to ISO 9917-1	Not measured by Doxa Conforms to ISO 9917-1**	SE
Dimensional change	<1%	<1%	SE
Acid soluble lead content	0.14 mg/kg Conforms to ISO 9917-1	Not measured by Doxa Conforms to ISO 9917-1**	SE
Net setting time	4-6 min Conforms to ISO 9917-1	6 min * Conforms to ISO 9917-1**	SE
Working time	>1 min Conforms to ISO 9917-1	1:30 min * Conforms to ISO 9917-1**	SE
Shear bond strength against dentin	Max: 17.0 MPa	Max: 8.7 MPa	SE
Thermal conductivity (at 37°C)	0.75 W/m K	0.58 W/m K	SE

Amount of heat generated during setting	40.2°C	41.7°C	SE
Fluoride release	Continuous for at least 28 days	Continuous for at least 28 days	SE

*Data from Riva Self Cure Instructions for Use

** Conformance with ISO 9917-1 is stated in the Riva Self Cure labelling

5.8 Non-clinical performance data

Differences in technological characteristics have been evaluated with performance testing and biological evaluation to show that Ceramir Restore QuikCap is as safe and effective as its predicate device.

Ceramir Restore QuikCap has been tested in accordance with the FDA guidance document “Dental Cements - Premarket Notification” and the FDA recognized performance standard ISO 9917-1:2007. Ceramir Restore QuikCap fulfills the applicable requirements and is similar in performance to the predicate device Riva Self Cure.

The biological evaluation of Ceramir Restore QuikCap was performed according to recognized consensus standards ISO 7405:2018, ISO 10993-1:2018 and ISO 10993-18:2020 in conjunction with the FDA guidance document “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"”. The evaluation concludes that the material does not raise any new questions of safety or effectiveness for its intended use and indications.

5.9 Substantial equivalence

Based on the information provided above, Ceramir Restore QuikCap is substantially equivalent to the Riva Self Cure predicate device. It is demonstrated that the minor differences between Ceramir Restore QuikCap and Riva Self Cure do not raise any new questions of safety or effectiveness.

The substantial equivalence is based on the similarities in intended use and indications, technological characteristics, performance characteristics and principles of operation with the Riva Self Cure predicate device.