SDI Limited
Ray Cahill
Chief Quality and Compliance Officer
3-13 Brunsdon Street
Bayswater, Victoria 3153, Australia

April 11, 2018

Re: K172047
Trade/Device Name: Riva Star
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: PHR
Dated: March 2, 2018
Received: March 7, 2018

Dear Ray Cahill:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mary S. Runner -S

forTina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172047

Device Name
Riva Star

Indications for Use *(Describe)*
Treatment of dentinal hypersensitivity.
For use in adults over the age of 21.

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.

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510(k) Summary K172047

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

1. Submitters information:

SDI Limited
3-13 Brunsdon Street, Bayswater, Victoria 3153, Australia

2. Contact information:

Ray Cahill
Chief Quality and Compliance Officer
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3. Device Information:

Proprietary Name:	Riva Star
Common name:	Tooth desensitiser
Classification Name:	Cavity varnish
Regulation Number:	21 CFR 872.3260
Product Code:	PHR
Classification:	Medical device, Class II

4. Date summary prepared: 2 March 2018

5. Primary Predicate device:

Riva Star is substantially equivalent to predicate device Advantage Arrest (K102973) by Elevate Oral Care, product code PHR.

6. Reference predicate devices:

Super Seal (K120109), D/Sense (K120176), Remesense (K082594), with Product Code LBH.

7. Indications for Use:

Treatment of dentinal hypersensitivity.
For use in adults over the age of 21.

8. Purpose and description Device Description and technological characteristics:

Riva Star is a two-component device made up of Riva Star Step 1, containing silver diamine fluoride liquid, and Riva Star Step 2, containing aqueous potassium iodide liquid.

Riva Star Step 1 silver diamine fluoride solution is applied to the tooth, immediately followed by Riva Star Step 2 aqueous potassium iodide, which forms an immediate reaction precipitate of silver iodide, thereby reducing tooth sensitivity by physically occluding the open dentinal tubules.

Riva Star as well as predicates are liquids or gels that are applied to the teeth using an applicator brush or similar application. With D/Sense, however, the product is in contact with the teeth by foam strips impregnated with the solution.

9. Comparison of technological characteristics:

The fundamental principle and mode of action of Riva Star and the predicate devices in reducing dentinal hypersensitivity is the occlusion of open dentin tubules by the formation of a precipitate.

Both Riva Star and primary predicate Advantage Arrest employ silver diamine fluoride as the main chemical to form the precipitate to occlude the open dentinal tubules. Riva Star, however, also uses a second component, potassium iodide solution, which allows for an immediate reaction precipitate of silver iodide to be formed to occlude the open dentinal tubules. Advantage Arrest, a one component device containing silver diamine fluoride, reacts with the hydroxyapatite of the tooth component. Upon reaction with the silver diamine fluoride, the calcium and phosphate of the hydroxyapatite are converted into calcium fluoride and silver phosphate, respectively to occlude the open dentinal tubules.

With the reference predicate devices Super Seal, D/Sense and Remesense, the oxalate reacts with the dentin calcium to form a deposit of calcium oxalate crystals to occlude the open dentinal tubules and thus reduce tooth sensitivity.

10. Comparison of Indications for Use:

This device is indicated for the treatment of dentinal hypersensitivity, for use in adults over the age of 21.

Its Indications for Use are identical to predicate device Advantage Arrest.

Although Riva Star's indications for use are not identical to the reference predicate devices, the differences in phrasing does not change the overall intended purpose as a tooth desensitiser.

11. Comparison to the Predicate Devices:

A comparison of Riva Star with the predicate devices is as follows:

	Subject device	**Primary predicate device**	**Reference predicate device**	**Reference predicate device**	**Reference predicate device**
	RIVA STAR	**ADVANTAGE ARREST**	**Super Seal**	**D/Sense**	**Remesense**
510(k) number	K172047	K102973	K120109	K120176	K082594
Company	SDI Limited	Elevate Oral Care (named as ADP Silver Dental Arrest, LLC in 510k)	Phoenix Dental, Inc	Centrix, Inc.	Remedent
Classification name	Cavity varnish	Cavity varnish	Cavity varnish	Cavity varnish	Cavity varnish
Common name	Tooth desensitiser	Tooth desensitiser	Tooth desensitiser	Tooth desensitiser	Tooth desensitiser
Regulation number	872.3260	872.3260	872.3260	872.3260	872.3260
Classification Product Code	PHR	PHR	LBH	LBH	LBH
Indications for	Treatment of	Treatment of	Assists in the	Dual-action	Relief of tooth

Use	dentinal hypersensitivity. For use in adults over the age of 21	dentinal hypersensitivity. For use in adults over the age of 21	removal of the smear layer, seals the tubules, desensitizes and functions as a re-wetting agent.	dentin desensitizer and cavity liner.	sensitivity
Technical method / characteristics:	Silver diamine fluoride and potassium iodide form a precipitate of silver iodide to block open dentinal tubules.	Silver diamine fluoride forms precipitates with calcium or phosphate in the dentinal tubules to block open dentinal tubules	Demineralises the organic and mineral debris of the smear layer and the outer most ring of peritubular dentin (the very hard mineralized dentin of each tubule complex) and restructures the demineralized material as a calcium oxalate precipitate. It creates an acid resistant layer bound both to the surface as well as into the dentinal tubules.	Reacts with the smear later to precipitate micro crystals of calcium oxalate and potassium nitrate. These crystals penetrate deeply into the tubules, and seal the entire dentinal surface with a continuous, acid-resistant complex.	Potassium oxalate breaks down into potassium and oxalic acid. The oxalic acid reacts with the calcium ions to form calcium-oxalate crystals. These crystals block the dentin tubules, thereby alleviating dental sensitivity.
Mode of action	Tubule occlusion	Tubule occlusion	Tubule occlusion	Tubule occlusion	Tubule occlusion
Material composition:	Silver diamine fluoride, Aqueous Potassium Iodide	Silver diamine fluoride	Oxalic acid, potassium salt	Potassium binoxalate, nitric acid, water.	Water, Glycerin, Dipotassium Oxalate, Aroma, EDTA, BHT, Sodium Hydroxide
Application:	liquid	liquid	gel	liquid	Tray/kit/gel
Rx / OTC	Rx	Rx	Rx	Rx	Rx

12. Non-clinical performance testing:

A Hydraulic Conductance study of Riva Star and Super Seal tooth desensitisers was conducted. The data demonstrated that Riva Star is an effective agent to reduce fluid flow through dentine, and is substantially equivalent to Super Seal in treating dentinal hypersensitivity. Scanning electron microscope (SEM) images showed both Riva Star and Super Seal formed a precipitate to occlude the open dentinal tubules.

A comparative 7-day in vitro fluoride and silver ion release study was conducted on Riva Star and the primary predicate device Advantage Arrest. The data showed that Riva Star released less fluoride and silver ions compared to Advantage Arrest, demonstrating that Riva Star is as safe as Advantage Arrest.

Biocompatibility testing was conducted according to ISO 10993-1:2009 - *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, ISO 7405:2008 – *Dentistry – Evaluation of biocompatibility of medical devices used in dentistry, and* FDA General Guidance on the Use of International Standard ISO 10993-1 (2016).

The tests carried out for Riva Star and standards applied for each test are as follows:
- Cytotoxicity (ISO Agarose, ISO Direct contact) - ISO 10993-5; IS0 7405

- Sensitisation (ISO Guinea Pig Maximization Sensitization) - ISO 10993-10
- Oral Mucosal Irritation (Hamsters, collar method, 7 day) - ISO 10993-10
- Oral Acute Toxicity (Mice – 7 day) - ISO 10993-11.

Riva Star has limited contact with dentine, being an externally communicating device.

The test carried out for predicate device Advantage Arrest and standards applied is as follows:
- Cytotoxicity (ISO Direct contact) - ISO 10993-5; IS0 7405

Riva Star and predicate device Advantage Arrest cytotoxicity testing produced equivalent results. Riva Star testing for irritation, sensitisation and acute oral toxicity provides evidence of biocompatibility.

Stability testing of Riva Star was conducted by evaluating the physical properties of the device to confirm a shelf life of 25 months when stored between 2ºC (35°F) to 8°C (45°F).

13. Clinical performance testing:

A double blind randomised clinical trial on patients with recognisable tooth sensitivity on both sides of their upper arch was performed, with Riva Star applied to the sensitive tooth on one arch, and predicate device Super Seal applied to the sensitive tooth on the other arch, and patients responses were recorded initially and following 1 week, on a visual analogue scale (VAS). The study showed that Riva Star was more effective than Super Seal in reducing dentine hypersensitivity after 7 days.

14. Conclusion:

The information presented in this submission, including composition, indications for use, mode of action and technological characteristics, biocompatibility, non-clinical and clinical performance testing, establishes that Riva Star is substantially equivalent to the predicate devices.