March 6, 2024

Kids-e-Dental LLP
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K240619
Trade/Device Name: e-SDF
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity varnish
Regulatory Class: Class II
Product Code: PHR
Dated: March 5, 2024
Received: March 5, 2024

Dear Prithul Bom:

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, MChE, RAC, CQIA
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

e-SDF

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.

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Kids-e-Dental™

510(k) Summary for e-SDF K240619

Date Summary was Prepared	February 20th 2024
510(k) Submitter	kids-e-dental LLP 411, Akruti Arcade, Jp Road, Opp A.H Wadia school, Andheri west, Mumbai, India400053 http://kids-e-dental.com/ +91-7506-038-332 drmukul@kids-e-dental.com
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Device Common Name	Tooth Desensitizer
Trade Name	**e-SDF**
Device Product Codes andClassification	Class II, PHR, 21 CFR 872.3260
Predicate Device	Silver Dental Arrest (Advantage arrest), K102973
Device Description	e-SDF is a single component liquid device made up of 38% silver diamine fluoride.Silver diamine fluoride solution is applied to the tooth, to reduce tooth sensitivity by physically occluding the open dentinal tubules. e-SDF is a liquid that is applied to the teeth using an applicator brush or similar application.
Indications for Use	Treatment of dentinal hypersensitivity. For use in adults over the age of 21.

Technological Characteristics

The intended use and key technological characteristics of e-SDF are substantially equivalent to that of the Predicate Device, Silver Dental Arrest (K102973).

A detailed comparison between the Subject Device and the Predicate Device is presented in the Table below-

Description	Subject Device e-SDF	Predicate Device Silver Dental Arrest (K102973)	Equivalency
Company Name	Kids-e-Dental LLP, India	Elevate Oral Care (named as ADP Silver Dental Arrest, LLC in 510k), USA	NA
Classification Name	Cavity Varnish	Cavity Varnish	Equivalent
Common Name	Tooth desensitiser	Tooth desensitiser	Equivalent
Indications for Use	Treatment of dentinal hypersensitivity. For use in adults over theage of 21.	Treatment of dentinal hypersensitivity. For use in adults over the age of21.	Similar
Classification Product Code & Regulation Number	PHR, 21 CFR 872.3260	PHR, 21 CFR 872.3260	Similar
Material composition	Silver diamine fluoride	Silver diamine fluoride	Similar
Mode of action	Tubule occlusion	Tubule occlusion	Similar
Application:	Liquid	Liquid	Similar
Technical method / characteristics:	Silver diamine fluoride forms precipitates with calcium or phosphate in the dentinal tubules to block open dentinal tubules	Silver diamine fluoride forms precipitates with calcium or phosphate in the dentinal tubules to block open dentinal tubules	Similar
Sterility, Packaging	Non-Sterile, Bulk Pack	Non-Sterile, Bulk Pack	Similar

Description	Subject Device e-SDF	Predicate Device Silver Dental Arrest (K102973)	Equivalency
OTC/Rx	Rx	Rx	Similar
Biocompatibility	Biocompatible as per ISO 10993-1	Biocompatible as per ISO 10993-1	Similar

Non-clinical performance testing

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

Biocompatibility testing was conducted according to ISO 10993-1:2018 - Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, ISO 7405:2018 – Dentistry – Evaluation of biocompatibility of medical devices used in dentistry, and FDA General Guidance on the Use of International Standard ISO 10993-1 (2020).

Conclusion:

e-SDF is deemed substantially equivalent to the Predicate Device, Silver Dental Arrest (Advantage arrest) (K102973) due to the similarities in intended use and function. Performance testing & Biocompatibility demonstrate that e-SDF is as safe and effective as the Predicate Device. The minor technological differences between e-SDF and the Predicate Device do not raise any questions on the safety and effectiveness of the Subject Device.