May 16, 2024

Tedequim SRL
% Juan Tezak
Consultant
Compliance 4 Devices
118 W Prive Cr.
Delray Beach, Florida 33445

Re: K240059
Trade/Device Name: FAgamin®
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: PHR
Dated: April 16, 2024
Received: April 16, 2024

Dear Juan Tezak:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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)*

K240059

Device Name

FAgamin®

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
K240059

Prepared May 14, 2024

I) Applicant

Submitter	TEDEQUIM SRL
Address	Bv. Los Polacos 6136. Córdova, X5147GGP. Argentina
Contact	Mrs. Leonor Pasteris
Telephone	+54 93515112131
E-mail	lpasteris@tedequim.com.ar

II) Device

Trade Name	FAgamin®
Common Name	Diammine Silver Fluoride Dental Hypersensitivity Varnish
Classification Name	Cavity varnish
Regulation Number	872.3260
Product Code	PHR

III) Predicate Device

510(k) Number	K102973
Applicant	Elevate Oral Care (named as ADP Silver Dental Arrest LLC in 510k)
Trade Name	Silver Dental Arrest
Classification Name	Cavity varnish
Regulation Number	872.3260

IV) Indication For Use

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

V) Device Description

FAgamin® is a professional treatment for dentin hypersensitivity. It is indicated for adults over 21 years of age.

FAgamin® is presented in a 5 ml black dropper bottle and contains a 38% w/v solution of diamine silver fluoride. Its design includes a secure screw cap and labeled container.

Table of specifications

Specifications		
Test/Assey	**Parameter**	**Specification**
Appearance	Appearance	Clear Liquid
Color	Color	colorless
Odor	Odor	ammonia
pH	pH	8 a 10
Density	Density (15°C)	1.25 a 1.35 g/ml
Vholard titration	Silver Ions Conc.	24.1- 26.8 % W/V

Specifications		
Test/Assey	**Parameter**	**Specification**
SDF titration	Silver Diamine Fluoride Conc.	36- 40% W/V
Potenciom. Selective ion elect.	Fluoride ion conc.	4.2 - 4.7 W/V
Microbiological Test	not applicable	not applicable
Stability test	Exp. Data	2 years

Composition:

Silver diamine fluoride (CAS34445-07-3): 38%

ammonium hydroxide (CAS 1336-21-6) and distilled water (CAS7732-18-5): 62%

VI) Comparison of Technological Characteristics

Specifications	Subject Device	Predicate Device	Discussion
Device name	Fagamin®	Advantage Arrest	N/A
510(k) Number	K240059	K102973	N/A
Company	Tedequim SRL	Elevate Oral Care (named as ADP Silver Dental Arrest LLC in 510k)	Different
Classification Name	Cavity Varnish	Cavity Varnish	Same
Common Name	Tooth Desensitizer	Tooth Desensitizer	Same
Regulation Number	872.3260	872.3260	Same
Classification	Class 2	Class 2	Same
Product Code	PHR	PHR	Same
Indications for Use	Treatment of dentinal hypersensitivity. For use in adult over the age of 21.	Treatment of dentinal hypersensitivity. For use in adult over the age of 21.	Same
Technical Method / Characteristics	FAgamin® reacts with calcium and phosphates to form precipitates that block the dentinal tubules	Advantage Arrest reacts with calcium and phosphates to form precipitates that block the dentinal tubules	Same
Mode of Action	Dentinal tubule obliteration.	Dentinal tubule obliteration.	Same
Material Composition	Silver diamine fluoride, Purified Water	Silver diamine fluoride Purified Water FD&C Blue 1	Similar
Color	Colorless	Blue	Different
% SDF	38%	38%	Same
Application	Liquid	Liquid	Same
pH	8 to 10	9.3	Superior
Density (15°C)	1.25 a 1.35 g/ml	1.275 g/ml	Similar
Rx / OTC	Rx	Rx	Same
Packaging	5 ml Black dropper bottle	Squeezable Dropper Bottle 8ml bottle Three 3ml bottle kit	Similar

Specifications	Subject Device	Predicate Device	Discussion
Fluoride Release	The maximum rate of fluoride release is 0.026 ppm/mm2	The maximum rate of fluoride release is 0.024 ppm/mm2	There is no significant difference between both SDF
SEM/ EDS Analysis	Deposites of silver, calcium, fluoride and phosphate were observed on dentin and blocking tubules.	Deposites containing silver, calcium and phosphate were observed on dentin and blocking tubules.	Same
Dentin Permeability	Dentin permeability was measured by means of hydraulic conductance. % Average FAgamin ± DS 34.51 ± 12.61	Dentin permeability was measured by means of hydraulic conductance. % Average FAgamin ± DS 30.72 ± 12.49	No significant differences between FAgamin® and Advantage Arrest p> 0.05.

FAgamin® and its predicate Silver Dental Arrest are very similar products in terms of their intended use, composition and efficacy in the treatment of dentin hypersensitivity.

VII) Summary of Non-Clinical Testing

Test	Purpose	Criteria	Result
Stability Test	To determine if the product remains stable during the proposed 2-year shelf life,	FAgamin® is physically and chemically stable in the proposed package for a period of 24 months	Pass
Dentin Hydraulic Conductance	To demonstrate that FAgamin® is a dentin desensitizer similar to Advantage Arrest by measuring hydraulic conductance.	There were no significant differences between FAgamin® and Advantage Arrest p> 0.05.	Pass
Fluoride release	To determine and compare the amount of fluoride release from FAgamin® and Advantage Arrest after application over teeth in vitro in water at 37°C during 7 days.	There are no significant differences between the two SDF in terms of fluorine ion release after application over teeth.	Pass
SEM- EDS	To compare the effect of FAgamin® and Advantage	FAgamin® is similar to Adantange Arrest and both SDFs are	Pass

Test	Purpose	Criteria	Result
	Arrest on phosphoric acid treated dentin.	desensitizing agents by obliterating the dentinal tubules with deposits containing silver, phosphorus and calcium.	
ISTA 3A	To evaluate the ability of a package to protect its contents during transport.	No external damage to the transport packaging was observed.	Pass
ISO 10993-5 Citotoxicity	To evaluate the cytotoxic potential of FAgamin®	Non-Cytotoxic from a dilution of 1/320,000.	Pass
Sensitization	To evaluate the sensitization potential of FAgamin®	It could not be demonstrated that the substance produces sensitization reactions.	Pass
Irritation	To evaluate the irritation potential of FAgamin®	Under the conditions of the study, not an irritant	Pass
ISO 10993-11 Sistemic Toxicity	To evaluate the Sistemic Toxicity potential of FAgamin®	The sample complies with the requirements of the assay	Pass

VIII) Summary of Clinical Testing

No clinical testing was performed in support of this submission.

IX) Conclusion

The conclusions drawn from the non-clinical testing demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K102973.