November 22, 2024

Jasberry Healthcare Private Limited
Balwant Rai
CEO, Chief Science Officer
162 Model Town
Kapurthala, Punjab 144401
India

Re: K242913
Trade/Device Name: Jasmate® Toothpaste
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH
Dated: September 24, 2024
Received: September 24, 2024

Dear Balwant Rai:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

FDA 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)*

K242913

Device Name

Jasmate® Toothpaste

Indications for Use *(Describe)*

Jasmate® Toothpaste is prescription fluoride dentifrice for use in the prevention and treatment of dental sensitivity.

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.

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K242913

Pre-market Notification 510(k) Summary

General Company Information

510(k) Submitter : Jasberry Healthcare Private Limited
Company Address : 162 Model town, Kapurthala, Punjab, India.
Contact Person Name : Dr. Balwant Rai
Title : CEO, Chief Science Officer
Contact Emails : raibalwant29@gmail.com, rai@jasberryhealthcare.com
Contact Number : +919888081234

Dated : 17-09-2024

Throughout the submission, there is mention of Jasmate® toothpaste, a dental sensitivity reduction device, representing the range of products covered under this 510(k) submission.

Device Information

Proprietary Name : Jasmate® toothpaste
Common or Usual Name : Cavity Varnish
Regulation Number : 21 CFR 872.3260
Regulation Name : Cavity Varnish
Regulatory Class : Class 2
Review Panel : Dental

Variants/Types: Jasmate® toothpaste is provided in the form of a fluoride-containing dentifrice.

Further Description of Jasmate® toothpaste
Jasmate® toothpaste is a fluoride-containing dentifrice designed for use in the prevention and treatment of dental sensitivity.

Indications for Use:
Jasmate® toothpaste is prescription fluoride dentifrice for use in the prevention and treatment of dental sensitivity.

Identification of the Predicate Device

S.No.	Subject Device	Predicate Device
1	Jasmate®	BioMin® Restore Plus (K200077)

Description of the Device Device Description:

Jasmate® toothpaste is a dentist and dental professional prescribed, daily-use, fluoride dentifrice to be used in the prevention and treatment of dental sensitivity through the physical occlusion of dentin tubules.

Sodium fluoride is absorbed by the surface of hydroxyapatite crystals on the teeth, which are needed for mineralization. This makes the teeth more resistant to demineralization by changing the apatite crystal solubility. Sodium fluoride inhibits the demineralization of teeth in a pH-related manner. Sodium fluoride and hydroxyapatite are active ingredients. When exposed environment, it undergoes a rapid surface reaction to form fluorapatite, which is chemically and structurally similar to natural tooth mineral, allowing it to physically occlude tubules.

Summary of Technological Characteristics

The fundamental principle and mode of action of Jasmate® toothpaste is the same as the predicate device. This device is designed to reduce dentinal hypersensitivity through the physical occlusion of open dentin tubules by the formation of an apatite layer. Potassium nitrate decreases the fluid flow through the tubules by clogging them, thereby decreasing the level of activity of dental sensory nerves and prevents or reduces the sensation signals from reaching the brain. Sodium fluoride is absorbed by the surface of hydroxyapatite crystals on the teeth, which are needed for mineralization. This makes the teeth more resistant to demineralization by changing the apatite crystal solubility. Sodium fluoride inhibits the demineralization of teeth in a pH-related manner.

Comparison of Technology Characteristics

The non-clinical study compared the performance and physical properties of **Jasmate® Toothpaste** with the predicate device **BioMinF® Toothpaste** to establish equivalence. The study evaluated key characteristics, including physical properties, dentin sensitivity performance, and tubule occlusion efficacy, as summarized below:

Physical Properties

- **Density, pH, Viscosity, Spreadability**: Jasmate® demonstrated statistically equivalent values compared to BioMinF®, confirming similar physical behavior, as reported in the In-vitro Study Report.
- **Foaming Power**: No significant difference was observed, indicating comparable user experience.

Dentin Sensitivity Performance

- **Relative Dentin Abrasion (RDA)**: Both toothpastes showed equivalent abrasiveness, ensuring safe and effective cleaning without excessive wear.
- **Enamel Fluoride Uptake (EFU)**: Significant improvements were observed post-treatment for both formulations, confirming comparable fluoride delivery and remineralization capabilities.

- **Enamel Solubility Reduction (ESR)**: Both products significantly reduced enamel solubility post-treatment, demonstrating similar efficacy in enhancing remineralization and protecting enamel.

Tubule Occlusion

- **Scanning Electron Microscopy (SEM)**: Post-treatment analysis revealed significant increases in dentin tubule occlusion for both products. Jasmate® achieved 80% occlusion in Grade A compared to BioMinF®'s 50%, suggesting superior occlusion capability, though grading scales differed between studies.

Active Ingredients

- Jasmate® utilizes **Sodium Fluoride (500 ppm)**, while BioMinF® contains **Fluoro Calcium Phospho Silicate**. Both active ingredients effectively address dentin hypersensitivity, with comparable mechanisms of action in tubule occlusion and nerve desensitization.

Overall, the non-clinical study establishes the equivalence of Jasmate® Toothpaste to BioMinF® Toothpaste in terms of physical properties, therapeutic performance, and safety.

Performance Tests

The formula of Jasmate® toothpaste was tested for its ability to reduce dentine hypersensitivity through physical occlusion of dentine tubules and its relative abrasion level of dentine and enamel. The dentine tubule occlusion test result indicates that Jasmate® toothpaste is as effective as the primary predicate device at dentine tubule occlusion. Meanwhile, the Relative Dentin Abrasivity (RDA) value is similar to the primary predicate and is well under the limit considered safe for daily use (<250) established by American Dental Association (ADA).

Non-Clinical Testing Summary for Jasmate® Toothpaste

To demonstrate the safety, performance, and substantial equivalence of Jasmate® Toothpaste, a series of non-clinical tests were conducted to evaluate its physical, chemical, and functional properties. The results from these tests indicate that Jasmate® Toothpaste meets the desired specifications and performance requirements for safe and effective use. Below is a summary of each test conducted and the respective findings:

1. Density: This test measured the material density to confirm uniformity and consistency, ensuring structural integrity. Jasmate® Toothpaste showed consistent density values, meeting the desired specification.
2. pH: pH testing assessed the acidity or alkalinity of the formulation, confirming compatibility with oral use. Results indicated the pH levels of Jasmate® Toothpaste were within the safe and effective range.
3. Viscosity: Viscosity testing verified the formulation's consistency, aiding in application and spreadability. Jasmate® Toothpaste demonstrated optimal viscosity, ensuring ease of use without separation.

4. Spreadability: Spreadability testing showed that Jasmate® Toothpaste spreads uniformly, enabling effective coverage on the intended surface, aligning with the desired outcome.
5. Foaming Power: This test measured the foaming ability, essential for a satisfactory cleansing action. Jasmate® Toothpaste achieved adequate foaming levels, meeting performance expectations.
6. Relative Dentin Abrasion (RDA): RDA testing indicated that Jasmate® Toothpaste's abrasiveness is within safe limits, minimizing the risk of enamel and dentin wear. The results met the standards for safety in abrasion.
7. Enamel Fluoride Uptake: Testing confirmed Jasmate® Toothpaste's capability to enhance fluoride uptake in enamel, contributing to improved resistance against decay, in line with the target performance.
8. Enamel Solubility Reduction: Enamel solubility reduction testing demonstrated Jasmate® Toothpaste's effectiveness in decreasing enamel solubility, offering protective qualities against demineralization as desired.
9. Scanning Electron Microscopy (SEM) Analysis of Tubule Occlusion: SEM analysis confirmed Jasmate® Toothpaste's effectiveness in occluding dentinal tubules, which helps reduce sensitivity. Results showed the product successfully achieved the desired tubule occlusion.

Biocompatibility

Different biocompatibility tests in accordance with ISO 10993 have been performed on the subject device.. The results of these tests and studies indicate there is no evidence of any hazardous effects and the subject device is safe for its intended use

Substantial Equivalence Comparison Table

S.No.	Characteristic	Jasmate® Toothpaste	BioMinF® Toothpaste	Conclusion
1	**Intended Use**	For dental hypersensitivity relief.	For dental hypersensitivity relief.	Equivalent
2	**Indications for Use**	Prescription fluoride dentifrice for the prevention and treatment of dental sensitivity.	Prescription fluoride dentifrice for the prevention and treatment of dental sensitivity.	Equivalent
3	**Design**	Paste/gel applied to the tooth using an applicator brush or similar application.	Paste/gel applied to the tooth using an applicator brush or similar application.	Equivalent
4	**Composition of Material**	Contains apatite-forming ingredients, hydroxyapatite,	Contains apatite-forming ingredients, hydroxyapatite,	Equivalent

		antioxidants, saliva-stimulating agents, fillers, surfactants, thickening agents, colorants, sweeteners, and flavor enhancers.	antioxidants, saliva-stimulating agents, fillers, surfactants, thickening agents, colorants, sweeteners, and flavor enhancers.	
5	**Technological Characteristics**	Physical occlusion of dentin tubules.	Physical occlusion of dentin tubules.	Equivalent
6	**Mechanism of Action**	Occludes dentin tubules through reaction with saliva and subsequent formation of an apatite layer and direct occlusion with pre-formed hydroxyapatite particles.	Occludes dentin tubules through reaction with saliva and subsequent formation of an apatite layer and direct occlusion with pre-formed hydroxyapatite particles.	Equivalent
7	**Biocompatibility**	Demonstrated biocompatibility.	Demonstrated biocompatibility.	Equivalent

Summary:

Jasmate® Toothpaste is substantially equivalent to BioMinF® Toothpaste in all evaluated characteristics, ensuring comparable safety, effectiveness, and functionality.

Conclusion:

Based on the comparison of the compositions and actions, as well as the testing data provided, Jasmate® toothpaste is considered to be substantially equivalent to the identified legally marketed predicate devices.