January 2, 2025

GreenMark Biomedical Inc.
% Rick Routson
Senior Project Manager
in2being, LLC
131 E Michigan Ave.
Suite E
Saline, Michigan 48176

Re: K241568
Trade/Device Name: CrystLCare™ PRO Biorestorative, Fluoride-Plus
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH
Dated: December 6, 2024
Received: December 6, 2024

Dear Rick Routson:

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,

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)*

K241568

Device Name

CrystLCare™ PRO Biorestorative, Fluoride-Plus

Indications for Use *(Describe)*

Indicated for relief of discomfort from dentin 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K241568

510(k) Summary

Prepared on: 2024-12-06

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	GreenMark Biomedical Inc.
Applicant Address	325 E Grand River Ave. Suite 314 East Lansing MI 48823 United States
Applicant Contact Telephone	(517) 896-3665
Applicant Contact	Dr. Steven Bloembergen
Applicant Contact Email	sb@greenmark.bio
Correspondent Name	in2being, LLC
Correspondent Address	131 E Michigan Ave. Suite E Saline MI 48176 United States
Correspondent Contact Telephone	(734) 645-9496
Correspondent Contact	Mr. Rick Routson
Correspondent Contact Email	rroutson@in2being.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CrystLCare™ PRO Biorestorative, Fluoride-Plus
Common Name	Cavity varnish
Classification Name	Varnish, Cavity
Regulation Number	872.3260
Product Code(s)	LBH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K062176	Relief ACP Oral Care Gel	LBH

Device Description Summary

21 CFR 807.92(a)(4)

CrystLCare™ PRO Biorestorative, Fluoride-Plus is a flavored dental strip which contains calcium, phosphate, and fluoride which are stabilized with a modified starch. The single-use strip is topically applied to the outer surface of a tooth or teeth that are experiencing dental sensitivity. The strip dissolves in saliva to release these minerals which then will precipitate into fluorohydroxyapatite crystals that form a layer over the tooth surfaces. This physically occludes exposed dentinal tubules and enamel porosities to relieve discomfort. The modified starch helps to stabilize the calcium, phosphate, and fluoride mineral components so that they can persist and penetrate into the dentinal tubules.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Indicated for relief of discomfort from dentin sensitivity.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same as the predicate, however the predicate's Indication for Use Statement also includes a description of its mechanism of action which was not retained for the subject device Indication for Use statement.

Technological Comparison 21 CFR 807.92(a)(6)

Both CrystLCare™ PRO Biorestorative, Fluoride-Plus and the predicate device, Relief ® ACP Gel, are intended to be used to treat the same condition, Dentinal Hypersensitivity. Both devices have the same mode of action in that they release mineral components in the presence of saliva, and the released minerals crystallize forming a mineral layer onto the tooth surface which physically occludes dentin tubules and enamel porosities. Both devices have the same chemical composition, including Sodium Fluoride, Potassium Nitrate, apatite forming ingredients (sources of calcium and phosphate ions), thickener, surfactant, flavorant, sweetener, and water. Both products are applied to the tooth surfaces in the area where sensitivity is experienced using a direct application method (direct placement of strip on teeth for subject device, brushing for predicate device).
There are minor technological differences between the subject and predicate devices. The application form is a dental strip for the subject device and a gel for the predicate device, however both devices release the mineral components in the presence of saliva. The subject device is a single component and does not require mixing, whereas the predicate device consists of 2 components contained in a dual barrel syringe that are mixed by means of a mixing nozzle tip at the point of care. The predicate device can also be applied using a tray method. The subject device is a single professional application, whereas the predicate device can be used 1-2 times daily at home for up to four weeks.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Fluoride Release testing determined that fluoride exposure from the CrystLCare™ PRO Biorestorative, Fluoride-Plus device was lower than the predicate device, however questions of safety or effectiveness are not raised. The ability of CrystLCare™ PRO Biorestorative, Fluoride-Plus to provide relief from tooth hypersensitivity was shown by non-clinical tests demonstrating that it physically occludes exposed dentin tubules. Scanning Electron Microscopy (SEM) micrographs of dentin samples treated by CrystLCare™ PRO Biorestorative, Fluoride-Plus were compared to micrographs of dentin treated with Relief© ACP Oral Care gel. The SEM micrographs of CrystLCare™ PRO Biorestorative, Fluoride-Plus and Relief© ACP Oral Care gel showed similar occlusion of the dentin tubules. Dentinal tubule occlusion was achieved by the deposition of a fluorohydroxyapatite layer onto the surface of the tooth, as was demonstrated by Electron Dispersive X-ray (EDX) spectroscopy and X-Ray Diffraction (XRD) analysis. Thus, CrystLCare™ PRO Biorestorative, Fluoride-Plus was shown to be as effective as the Relief© ACP Oral Care gel predicate device in occluding dentin tubules.

Clinical Testing - Not Applicable

Non-clinical performance testing and biocompatibility testing demonstrated that the device is as safe and effective as the predicate device. CrystLCare™ PRO Biorestorative, Fluoride-Plus is substantially equivalent in intended use, materials, principles of operation, and raises no new issues of safety or effectiveness.