March 29, 2021

GreenMark Biomedical Inc.
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K200601
Trade/Device Name: LumiCare Caries Diagnostic Rinse
Regulation Number: 21 CFR 872.1740
Regulation Name: Caries detection device
Regulatory Class: Class II
Product Code: LFC, EAQ
Dated: March 24, 2021
Received: March 26, 2021

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, M.ChE.
Assistant Director
DHT1B: Division of Dental 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200601

Device Name
LumiCare^TM Caries Detection Rinse

Indications for Use *(Describe)*
To aid the dental professional in visualization of carious lesions

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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"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) Summary

I. SUBMITTER

GreenMark Biomedical Inc.

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East Lansing, MI 48823

Offices and lab at:
1600 Huron Parkway,
Ann Arbor, MI 48109

Phone: 517-896-3665
Contact Person: Steven Bloembergen: info@greenmark.bio
Date Prepared: March 24, 2021

II. DEVICE

Name of Device: LumiCare™ Caries Detection Rinse
Common or Usual Name: Caries detector
Classification Name: Caries Detection Device (21 CFR 872.1740)
Regulatory Class: II
Product Code: LFC
Review Panel: Dental

III. PREDICATE DEVICE

Pulpdent Snoop™ Caries Detecting Dye, K964430

IV. DEVICE DESCRIPTION

The LumiCare™ device is an oral rinse solution containing starch-based particles tagged with fluorescein. A specific volume is swished in the mouth, followed by a water rinse and air drying of teeth prior to exposure of the teeth to a blue light source with an irradiance of 450 mW/cm^2 and wavelength of 450-470 nm. The clinician completes the clinical examination by observing fluorescence through light orange filter accessories, including protective eyewear, to aid the visualization of dental caries.

V. INDICATIONS FOR USE / INTENDED USE

LumiCare™ Caries Detection Rinse is indicated to aid the dental professional in visualization of carious lesions.

The Indications for Use statement for the LumiCare™ device is identical to that of the predicate device, with minor exception. This difference does not alter the intended use of the device nor does it affect the safety and effectiveness of the device relative to the predicate.

Both the subject and predicate device have the same intended use of detection of dental caries.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1. Comparison to Predicate Device

Characteristic	Subject Device	Predicate Device
Device Name	LumiCare™ Caries Detection Rinse	Pulpdent Snoop™ (K964430)
Regulation Number	872.1740	872.1740
Identification	Caries Detection Device	Caries Detection Device
Intended Use	Detection of dental caries	Detection of dental caries
Indication for disease	Dental caries	Dental caries
Indication for patient population	Adults and children	Not specified
Indication for Use statement	To aid the dental professional in visualization of carious lesions	To assist the dental professional in the detection of carious dentin
Anatomic Sites	Directly visible tooth surfaces	Directly visible tooth surfaces
Use Environment	Dental Operatory	Dental Operatory
Prescription/OTC	Prescription only	Prescription only
Product Form	Liquid	Liquid
Primary Carrier Fluids	Propylene Glycol/Water	Propylene Glycol/Water
Contains Staining Agent	Yes	Yes
Use	Apply product to teeth	Apply product to teeth
Detection Method	Areas of tooth decay temporarily stain	Areas of tooth decay temporarily stain
Shelf Life	2 years	2 years
Staining Agent	Fluorescein	Dark blue dye

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Characteristic	Subject Device	Predicate Device
Carrier for staining agent	Submicron Starch Particle	None
Viewing Conditions	Blue light/orange filter	Ambient light/white light with the naked eye or under magnification
Stimulation Wavelength	Blue light (450-470 nm, peak value)	Visible light

The subject and the predicate device are both dye-containing liquids which bind to carious lesions on all (occlusal, facial, lingual, proximal) directly visible surfaces of the teeth, providing a visible indicator of the presence of caries. The subject and predicate devices have similar technological elements: liquid formulation, application directly to teeth and the liquid contains carriers, preservatives, and a staining agent.

Technological differences between the subject and predicate device include:

1. Viewing Conditions: The predicate device's stain is visible under visible light whereas the subject device's stain is visible under blue light conditions when viewed through an orange filter. This difference does not impact safety or performance.
2. Staining agent and carrier: The subject device contains submicron starch particles as a carrier for the staining agent, fluorescein, whereas the predicate contains blue dye with no carrier. This difference does not impact safety or effectiveness. The fluoresceinated starch particle was demonstrated to be non-cytotoxic, non-irritating and non-sensitizing.

VII. PERFORMANCE DATA

A. Non-Clinical Performance Testing

Bench Testing

Sensitivity and Specificity testing was completed on extracted teeth using histologic reference standard for the LumiCare™ rinse and the predicate, demonstrating a high degree of reproducibility for the LumiCare™ rinse, and performance comparable to the predicate device. No FDA-recognized standards were available to inform the testing.

Simulated Use Testing

Simulated use testing in a clinical environment was performed by clinicians using a manikin model with extracted teeth placed in a typodont, demonstrating ease and effectiveness of use within the clinical workflow. No FDA-recognized standards were available to inform the testing.

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Biocompatibility

A biocompatibility risk assessment was performed (per 2016 FDA Biocompatibility Guidance), along with cytotoxicity, sensitization, and irritation testing (per ISO 10993-5 and 10993-10), indicating the LumiCare™ rinse is biocompatible for use as intended.

Shelf Life Testing

Based on accelerated testing, a shelf life of two years is supported. Real time aging is being performed. No FDA-recognized standards were available to inform the testing.

B. Clinical Performance Testing

Clinical performance testing was not conducted.

VIII. CONCLUSION

Based upon the indications for use and comparison of technology, together with the results from non-clinical performance testing, we find the LumiCare™ rinse used together with a blue light source, having an irradiance of 450 mW/cm^2 and wavelength of 450-470 nm, is substantially equivalent to the predicate device Pulpdent Snoop™.

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