May 16, 2023

Incisive Technologies Pty Ltd
% Melissa Burbage
Senior Regulatory Specialist
PaxMed International, LLC
12264 EL Camino Real, Suite 400
San Diego, California 92130

Re: K222560
Trade/Device Name: BlueCheck™ Caries Detection & Monitoring
Regulation Number: 21 CFR 872.1740
Regulation Name: Caries Detection Device
Regulatory Class: Class II
Product Code: LFC
Dated: May 1, 2023
Received: May 3, 2023

Dear Melissa Burbage:

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, M.ChE.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222560

Device Name

BlueCheck™ Caries Detection & Monitoring

Indications for Use *(Describe)*

To aid the dental professional in the 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

K 222560

BlueCheck™ Caries Detection & Monitoring

Incisive Technologies Pty Ltd

May 1, 2023

ADMINISTRATIVE INFORMATION

Manufacturer Name	Incisive Technologies Pty Ltd Level 4, 71 Collins Street Melbourne, Victoria, Australia Telephone: +61 (0)3 9653 3777
Official Contact	Kerry A. Hegarty, PhD; CEO
Representative/Consultant	Melissa Burbage, Senior Regulatory Specialist Kevin A. Thomas, PhD; Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: mburbage@paxmed.com kthomas@paxmed.com, flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	BlueCheck™ Caries Detection & Monitoring
Common Name	Device, Caries Detection
Regulation Number	21 CFR 872.1740
Regulatory Class	Class II
Product Code	LFC
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1B (Dental and ENT Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate Device:
K200601, LumiCare™ Caries Detection Rinse, GreenMark Biomedical, Inc.

Reference Device:
K955445, Caries Finder, Danville Engineering, Inc.

INDICATIONS FOR USE STATEMENT

To aid the dental professional in the visualization of carious lesions.

SUBJECT DEVICE DESCRIPTION

BlueCheck™ Caries Detection & Monitoring is a solution containing colored agents that, when applied to tooth surfaces following a dental prophylaxis procedure, binds to surface and subsurface porosities utilizing natural hydroxyapatite-binding chemistry of the protein component of the device. This allows dental professionals to observe the visual change in tooth surface color as blue on accessible tooth surfaces. BlueCheck is intended to be used in routine dental examinations as a diagnostic tool that assists dental professionals to visualize and assess caries. BlueCheck is supplied as a liquid product in single use vials (in a pack of 10 vials).

PERFORMANCE DATA

Non-clinical testing data submitted to demonstrate substantial equivalence included: shelf life testing, biocompatibility evaluation and testing according to ISO 10993-1, and performance testing compared to predicate and reference devices.

Performance studies were conducted to demonstrate that the subject device has been removed from the tooth surface after rinsing, brushing with toothpaste containing sodium lauryl sulfate (SLS) and action of saliva.

Risk assessments and viral inactivation studies were performed according to FDA's guidance *Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices)* issued on March 15, 2019.

EQUIVALENCE TO MARKETED DEVICES

All devices use a stain in a liquid that is able to penetrate the subsurface of caries (active) lesions and bind either to the hydroxyapatite via electrostatic forces (subject device and primary predicate device) or to denatured collagen (reference device). Non-bound product is removed by rinsing with water. The remaining product is visible to the dental professional, as it contains a staining agent bound to a carious lesion. For the subject device, bound product is removed by brushing with a toothpaste containing SLS and by action of saliva.

Characteristic	Subject Device	Predicate Device	Reference Device
	BlueCheck Caries Detection and Monitoring Incisive Technologies Pty Ltd	K200601 LumiCare™ Caries Diagnostic Rinse GreenMark Biomedical Inc.	K955445 Caries Finder Danville Engineering, Inc.
Reason for Predicate/Reference	n/a	Similar indications Performance comparison	Similar indications Performance comparison Use of color staining agent
Product Code	LFC	LFC, EAQ	LFC
Regulation Number	872.1740	872.1740	872.1740
Identification	Caries Detection Device	Caries Detection Device	Caries Detection Device
Intended Use	Detection of dental caries	Detection of dental caries	Detection of dental caries
Indication for Use Statement	To aid the dental professional in the detection and monitoring of dental caries.	To aid the dental professional in visualization of carious lesions	A visual aid for the detection of carious dentin.
Indication for Disease	Dental caries	Dental caries	Dental caries
Indication for Patient Population	Adults and children	Adults and children	Not specified
Anatomic Sites	Directly visible tooth surfaces	Directly visible tooth surfaces	Directly visible tooth surfaces
Use Environment	Dental Operatory	Dental Operatory	Dental Operatory
Product Form	Liquid	Liquid	Liquid
Primary Carrier Fluids	Phosphate Buffered Saline (PBS)	Water with Propylene Glycol	Water with Propylene Glycol
Contains Staining Agent	Yes	Yes	Yes
Staining Agent	Deep-blue dye (Amido black)	Fluorescein	Red color: acid red 52 Green color: FD&C green
Carrier for Staining Agent	Submicron Protein (Bovine Hemoglobin)	Submicron Starch Particle (cationic)	None
Application	Product is applied to teeth with an applicator/brush.	Product is poured into mouth and patient instructed to rigorously swish	Product is applied to teeth with an applicator/brush.
Detection Method	Areas of tooth decay temporarily stain	Areas of tooth decay temporarily stain	Areas of tooth decay temporarily stain
Viewing Conditions	Ambient light/white light with the naked eye or under magnification	Blue light/orange filter	Ambient light/white light with the naked eye or under magnification

Characteristic	Subject Device	Predicate Device	Reference Device
	BlueCheck Caries Detection and Monitoring Incisive Technologies Pty Ltd	K200601 LumiCare™ Caries Diagnostic Rinse GreenMark Biomedical Inc.	K955445 Caries Finder Danville Engineering, Inc.
Reason for Predicate/Reference	n/a	Similar indications Performance comparison	Similar indications Performance comparison Use of color staining agent
Stimulation wavelength	Visible light	Blue light (450-470 nm, peak value)	Visible light
Prescription/OTC	Prescription only	Prescription only	Prescription only
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use

CONCLUSION

Based on a comparison of the indications for use and technology, BlueCheck is substantially equivalent to LumiCare™ Caries Diagnostic Rinse, K200601.