March 20, 2025

Meridian Bioscience, Inc.
Whitney Rooker
Senior Regulatory Affairs Specialist
3471 River Hills Drive
Cincinnati, Ohio 45244

Re: K243922
Trade/Device Name: Revogene
Regulation Number: 21 CFR 862.2570
Regulation Name: Instrumentation For Clinical Multiplex Test Systems
Regulatory Class: Class II
Product Code: OOI
Dated: December 19, 2024
Received: December 20, 2024

Dear Whitney Rooker:

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 and Part 809); 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,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
OPEQ: Office of Product Evaluation and Quality
CDRH: 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.

510(k) Number *(if known)*
K243922

Device Name
Revogene

Indications for Use *(Describe)*
The Revogene® instrument is intended for *in vitro* diagnostic (IVD) use in performing nucleic acid testing of specific IVD assays in clinical laboratories. Revogene is capable of automated lysis and dilution of samples originating from various clinical specimen types. Revogene performs automated amplification and detection of target nucleic acid sequences by fluorescence-based real-time PCR.

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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3471 River Hills Drive
Cincinnati, Ohio 45244
meridianbioscience.com

Revogene®

510(k) Summary
Meridian Bioscience

A. Applicant Information

Date of preparation:	March 12, 2025
Submitter Information:	Meridian Bioscience, Inc. 3471 River Hills Drive Cincinnati, Ohio 45244
Contact Person:	Whitney Rooker Senior Regulatory Affairs Specialist Meridian Bioscience, Inc. Tel: 513.310.4134 Email: Whitney.Rooker@meridianbioscience.com

B. Proprietary and Established Names

Revogene®

C. Regulatory Information

Trade Name:	Revogene®
Common name:	Revogene instrument
K number:	K243922
Regulation Number:	21 CFR 862.2570
Regulation Name:	Instrumentation for clinical multiplex systems
Regulatory Classification:	Class II
Product Code:	OOI – Real-time nucleic acid amplification system
Panel:	Clinical Chemistry (75)

D. Purpose of Submission

This 510(k) Premarket Notification is meant to obtain FDA clearance for a modified version of the Revogene instrument cleared under K222779. A cooling system to reduce the temperature around the photomultiplier tube (PMT) and associated firmware updates are added to mitigate the risk of PMT glitches and Revogene blocking. In addition, the Operating System was upgraded to Windows 10. The Revogene System Software was upgraded to a

version compatible with Windows 10. These changes do not affect the device's intended use nor alter the device's fundamental technological characteristics.

E. Intended Use

Intended Use:	The Revogene® instrument is intended for *in vitro* diagnostic (IVD) use in performing nucleic acid testing of specific IVD assays in clinical laboratories. Revogene is capable of automated lysis and dilution of samples originating from various clinical specimen types. Revogene performs automated amplification and detection of target nucleic acid sequences by fluorescence-based real-time PCR.
Indications for Use:	See Intended Use statement.
Special Conditions for Use Statement:	For prescription use only For *in vitro* diagnostic use only
Special Instrument Requirements:	MOCK PIE (optional)

F. Device Description

The Revogene is a PCR instrument that automates lysis and dilution of samples, followed by nucleic acid amplification, and detection of target sequences by fluorescence-based real-time PCR. Revogene runs are orchestrated by a combination of software, firmware and instrument control protocol that ensures the adequate combination of incubation times and temperatures for sample homogenization and PCR analysis. The Revogene instrument acquires fluorescence signals generated during amplification. The signals are then interpreted by the system using embedded calculation algorithms.

The Revogene requires the use of a 'PIE', i.e., an assay-specific cartridge to which a patient sample is added. The PIE contains the reagents needed to process a sample and to perform a PCR amplification. When the number of assay PIEs to be run is lower than eight, the user fills empty spaces with "MOCK PIE", which are cartridges that simulate the presence of an assay PIE to confer thermal and rotational balance.

The Revogene instrument subject of this Premarket Notification is substantially equivalent to the Revogene instrument cleared under K222779. Meridian is submitting this 510(k) Premarket Notification to implement a photomultiplier tube (PMT) cooling system. This cooling system keeps the PMT environment at a temperature that prevents the appearance of fluorescence glitches, which may stop the Revogene instrument

G. Substantial Equivalence Information

Predicate device: Revogene®

Predicate Device Number: K222779

Comparison with Predicate:

Item	Modified Device **Revogene®** **(K243922, subject of 510(k) Premarket Notification)**	Predicate Device **Revogene® (K222779)**
Similarities		
Classification	Class II	Same
Intended Use	The Revogene® instrument is intended for *in vitro* diagnostic (IVD) use in performing nucleic acid testing of specific IVD assays in clinical laboratories. Revogene is capable of automated lysis and dilution of samples originating from various clinical specimen types. Revogene performs automated amplification and detection of target nucleic acid sequences by fluorescence-based real-time PCR.	Same
Sample Preparation Method	Automated cell lysis, DNAamplification and DNA detection	Same
Mode of Operation	Real-time Polymerase chain reaction with fluorogenic detection of amplified DNA	Same
Sample analysis and result determination	Combination of software, instrument control protocols and assay definition files developed and determined by Meridian	Same
Automatic Assay	Yes-result interpretation	Same
Sample identification	The instrument has two barcode readers to identify reagents and patient specimens. It provides traceability of the sample identification (ID) to the PIE ID, Sample Buffer Tube ID, and assay ID.	Same
Internal Process Control DNA assays	Each PIE contains an internal process control (PrC) that controls for amplification inhibition, assay reagents, and sample processing effectiveness.	Same
Internal Process Control RNA assays	Each PIE contains an Internal Control (IC) that controls for amplification inhibition, and assay reagents effectiveness.	Same

Item	Modified Device	Predicate Device
	Revogene® **(K243922, subject of 510(k) Premarket Notification)**	**Revogene® (K222779)**
	Sample processing is monitored by a Microfluidic Control (MFC).	
External Control	Materials available commercially but not required to run the test	Same
DNA Extraction	Cell lysis	Same
Specimens per run	Processes and analyzes up to 8 specimens per run (8 PIEs)	Same
Assay Cartridge	One sample per PIE	Same
Single Use	PIE can be used only once	Same
Instrument Optical Channels	Contains 4 optical channels	Same
Instrument Calibration	The instrument is factory calibrated by the manufacturer and will undergo performance qualification testing on-site during annual preventive maintenance. If qualification testing results determine significant drift, the instrument will be returned to the manufacturer for recalibration.	Same
Temperature Control	Heating element/fan assembly and cooling fan for PCR cycling.	Same
Differences		

Operating System	Windows® 10 IoT Enterprise (Windows 10)
	- OS image based on Windows 10
	- Update Revogene System Software to ensure:
	  - compatibility with Windows 10.
	  - compatibility with Third Party/Off the Shelf Software
	- Update the Off the Shelf Software managing the Revogene database.
	- Deactivation of internet explorer to prevent unintended access to internet.
	- Addition of a "NoAutoUpdate" key in Windows registry to prevent automatic updates from being installed.
		Windows® Embedded Standard 7 (Windows 7)

Item	Modified Device	Predicate Device
	Revogene® (K243922, subject of 510(k) Premarket Notification)	**Revogene® (K222779)**
Temperature Control	PMT cooling system	No PMT cooling system

H. Performance Characteristics

Functional testing has been conducted using contrived and negative samples in relevant clinical matrix using the following assays, which are representative of the Revogene assays currently on the US market: Revogene® Strep A, Revogene® Carba C and Revogene® SARS-CoV-2 assays. No statistically significant differences were observed between the Revogene instruments with and without PMT cooling system for the Positivity/Negativity rates, the Unresolved and Indeterminate results rates and the mean Ct values.

Testing was also carried out to demonstrate that the cooling system reduced the occurrence and amplitude of glitches. The activation of the PMT cooling system resulted in lower glitch amplitude compared to the amplitude documented on instruments run without cooling. No run triggered the prompting of a PMT error signal.

Finally, Revogene equipped with Windows 10 and with upgraded Revogene System Software operates as expected and yields expected assays results.

I. Proposed Labeling

The labeling is sufficient, and it satisfies the requirements of 21 CFR Part 809.

J. Conclusion

The submitted information demonstrates that the Revogene instrument equipped with the PMT cooling system is safe, effective, and substantially equivalent to the legally marketed device.