July 11, 2022

Meridian Bioscience, Inc
Jack Rogers
Regulatory Affairs Principal
3471 River Hills Drive
Cincinnati, Ohio 45244

Re: K220480
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: February 17, 2022
Received: February 18, 2022

Dear Jack Rogers:

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 and Part 809); 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,

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief,
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K220480

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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510(k) SUMMARY
INSTRUMENT ONLY

A. Applicant Information

Submission Date:	February 17, 2022
Submitter Information:	Meridian Bioscience, Inc. 3471 River Hills Drive Cincinnati, Ohio 45244
Contact Person:	Jack Rogers Regulatory Affairs Principal Meridian Bioscience, Inc Tel: 513-271-3700 Email: Jack.Rogers@meridianbioscience.com

B. Proprietary and Established Names

Revogene®

C. Regulatory Information

Trade Name:	Revogene®
Common name:	Revogene instrument
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
Panel:	Clinical Chemistry

D. Purpose of Submission

To update the current Revogene® software with a PMT surveillance algorithm that includes an improvement to the Revogene System Software's management of fluorescence results. This change does not affect the device's intended use nor alter the device's fundamental scientific technology.

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 (use if less than 8 samples processed in a single run)

F. Device Modification Description

The Revogene was previously cleared under K170558. Meridian Biosciences, Inc. is submitting this 510(k) to implement a software modification to the Revogene that updates the current software with a PMT surveillance algorithm. The software monitors raw data fluorescence signal during assay testing and identifies issues due to a malfunction of the photomultiplier tube (the "PMT"), a key component in the Revogene instrument's optics system used in the management of fluorescence signals. Upon detection of a PMT malfunction, the PMT surveillance algorithm software produces a specific error code to the user labeled "Detection Error" and will lock the instrument thereby preventing further use.

G. Substantial Equivalence Information

Predicate device:	Revogene®
Predicate Device Number:	K170558

Comparison with Predicate:

Item	**Modified Device**	**Predicate Device**
	Revogene® (Subject of 510(k))	**Revogene® (K170558)**
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

Item	Modified Device	Predicate Device
	Revogene® (Subject of 510(k))	**Revogene® (K170558)**
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
Level of Concern	Moderate	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 ID to the PIE ID, SBT 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. Sample processing is monitored by a Microfluidic Control (MFC).	Same
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 system 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 re-calibration.	Same
Software Change	Update of the current software with a PMT surveillance algorithm	-

H. Performance Characteristics

1. Analytical Performance

   See K170558 (Revogene Instrument), K170557 (Revogene GBS LB), K172569 (Revogene C. difficile), K183366 (Revogene Strep A), and K190275 (Revogene Carba C) .

2. Clinical Performance

   See K170558 (Revogene Instrument), K140557 (Revogene GBS LB), K172569 (Revogene C. difficile), K183366 (Revogene Strep A), K190275 (Revogene Carba C)

I. Conclusion

The submitted information demonstrates that the modified Revogene instrument is safe, effective, and substantially equivalent to the legally marketed device.