510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K220480

B Applicant

Meridian Bioscience, Inc

C Proprietary and Established Names

Revogene

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
OOI	Class II	21 CFR 862.2570 - Instrumentation For Clinical Multiplex Test Systems	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for 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.

B Type of Test:

Real-time PCR

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for 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.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:
The Revogene instrument was cleared under K170558 and is used with the following Revogene cleared assays:

- Revogene GBS LB (cleared on May 25, 2017 under the name of GenePOC GBS LB, K170557, software version 3.1.5 and firmware version 0.3.4);
- Revogene *C. difficile* (cleared on November 22, 2017 under the name of GenePOC CDiff, K172569, software version 3.2.1 and firmware version 0.3.4);
- Revogene Strep A (cleared on March 6, 2019 under the name of GenePOC Strep A, K183366, software version 4.0.10 and firmware version 2.1.0);
- Revogene Carba C (cleared on May 10, 2019 under the name of GenePOC Carba, K190275, software version 4.0.10 and firmware version 2.1.0)

Briefly, the Revogene instrument is similar to a low-speed centrifuge to which are attached the necessary components to perform the different steps of the diagnostic tests. It uses a disposable microfluidic cartridge (named PIE) that contains the reagents required for analyte detection. The Revogene can process from one (1) up to a maximum of eight (8) samples simultaneously in the same run. The instrument must contain eight (8) PIEs. If eight (8) PIEs are not available, empty spaces should be filled with MOCK PIEs.

The Revogene System is composed of the following:

- The Revogene instrument
- Revogene IVD Assays
- MOCK PIEs [A MOCK PIE mimics a test PIE and is used to complete the rotor when less than eight (8) samples are processed in a single run. MOCK PIEs help maintain the thermodynamic balance within a run]

In K220480, the device has been modified to implement a software change to 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'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.

Please refer to K170558 for additional information about the Revogene System.

B Instrument Description Information:

1. Instrument Name:

   Revogene

2. Specimen Identification:

   See K170558

3. Specimen Sampling and Handling:

   See K170558

4. Calibration:

   See K170558

5. Quality Control:

   See K170558

V Substantial Equivalence Information:

A Predicate Device Name(s):
Revogene

B Predicate 510(k) Number(s):
K170558

C Comparison with Predicate(s):

Device & Predicate Device(s):	K220480 (Subject Device)	K170558 (Predicate Device)
Device Trade Name	Revogene	Revogene
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Revogene instrument is intended for *in vitro* diagnostic (IVD) use in performing nucleic acid testing of specific IVD assays in clinical	Same

	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.	
Sample Preparation Method	Automated cell lysis, DNA amplification and DNA detection	Same
Mode of Operation	Real-time Polymerase chain reaction with fluorogenic detection of amplified DNA	
Sample analysis and result determination	Combination of software, instrument control protocols and assay definition files developed and determined by firm	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
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 it 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
General Device Characteristic Differences		
Software Change	Update of the current software with a PMT surveillance algorithm	

VI Standards/Guidance Documents Referenced:

ISO 14971:2019—Medical devices - Applications of risk management to medical devices

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

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

2. Linearity:

   N/A

3. Analytical Specificity/Interference:

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

4. Accuracy (Instrument):

   N/A

5. Carry-Over:

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

B Other Supportive Instrument Performance Characteristics Data:

Software Change
The software change is for the addition of a surveillance algorithm to the Revogene System Software capable of detecting glitches associated with the PMT. This algorithm will prevent the processing of raw data presenting glitches by the Results Processor and thus will minimize the reporting of potential false-positive results. Verification and validation activities were performed to ensure outputs met design inputs and that the Revogene System Software (version 4.3.4), as a portion of the Revogene platform, met user needs, the intended use, and software requirements.

PMT Surveillance Algorithm Performance
The PMT surveillance algorithm design was assessed by running the algorithm on a dataset constituting 593 runs, of which 500 runs were identified as normal runs that presented no PMT glitches.

The PMT surveillance algorithm was able to:

- Identify correctly 100% of the normal runs
- Identify the glitches in 83 out of 93 runs with PMT failures (89.2%)
- Identify the glitches in 27 runs out of 29 runs with PMT failures leading to false positive results (93.1%).

The surveillance algorithm was shown to flag instruments containing a faulty PMT and was observed to have no impact on instruments that do not generate glitches. Detection error messages were shown where glitches related to the PMT issue were identified. Testing indicated that software version 4.3.4 could successfully process a multi-assay run, and therefore, has no impact on the compatibility between the various Revogene assays.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.