510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

K170558

B. Purpose for Submission:

New instrument for use with the GenePOC GBS LB Assay cleared under K170557

C. Manufacturer and Instrument Name:

GenePOC Inc., revogene

D. Type of Test or Tests Performed:

Real-time PCR

E. System Descriptions:

1. Device Description:

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 consists of a rotor to spin the disposable microfluidic cartridge (referred to as "PIE"), two temperature controllers, a multichannel optical excitation source, a fluorescence detector, a tactile user-friendly interface, two barcode readers, integrated firmware, and software to deliver results to the user. The revogene instrument can detect up to four different florescence reporters. The instrument fully automates and integrates sample lysis, dilution, amplification and detection of the target sequence in complex samples using real-time PCR. User intervention is required for discharging the patient specimen into the Sample Buffer Tube (SBT), transferring the sample into the PIE and loading/unloading the PIE into the revogene instrument. The revogene can process from one up to a maximum of eight samples simultaneously in the same run; however, each run requires eight PIEs in the instrument. When fewer than eight samples are being processed, MOCK PIEs are included to bring the total to eight PIEs. Alternatively, assay PIEs loaded with sample buffer or with an external control can be used to bring the number of PIEs to eight. On completion of a run, the user removes the processed PIEs from the instrument and discards them according to normal biological waste management procedures. The results are displayed on the touchscreen user interface or transmitted to HIS/LIS (laboratory information system) where result outcomes are reported as Positive, Negative, Indeterminate, or Unresolved.

2. Principles of Operation:

a. Device Features Controlled by Software:

The GenePOC System Software works in conjunction with other software components, such as the firmware control, power firmware, and assay software that contribute to the functioning and results reporting by the instrument. The revogene software is responsible for instrument interaction with the user, assay workflow, traceability management, data analysis/storage, and communication with a LIS. The firmware manages the critical processes of the instrument and performs the required steps to obtain the diagnostic results, such as heating, cooling, centrifugation, and detection. The GenePOC System Software utilizes assay definition files that contain assay-specific parameters to run/report sample results. The PIE can be identified by the revogene software from its barcode.

The final software version reported for K170557 submission was V3.1.5 and 0.3.4 for the firmware. GenePOC reported that biological validation tests were conducted to confirm equivalency between the IUO version and IVD (commercial) version of the revogene.

b. Operational Environment (Off-the-Shelf Software):

The revogene system software uses a number of commercial Off-the-Shelf (OTS) software components. The sponsor provided detailed documentation for the OTS used, including validation studies.

3. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes ___x___ or No _____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes _____ or No ___x___

4. Specimen 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.

5. Specimen Sampling and Handling:

   Samples are manually prepared according to the assay manufacturer's suggestions and are transferred to an assay specific PIE for analysis. Briefly, the user is required for pipetting the patient specimen into the SBT, transferring the sample into the PIE, and loading/unloading the PIEs into the instrument.

6. 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.

7. Quality Control:

   Each PIE contains an internal process control that helps monitor for amplification inhibition, quality of assay reagents, and sample processing effectiveness. External controls must be created by the user. See K170557 for details.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes ___x_____ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 862.2570 Instrumentation for clinical multiplex test systems

2. Classification:

   Class II (special controls)

3 Product code:

   OOI – Real-time nucleic acid amplification

4. Panel:

   Chemistry (75)

G. Intended Use:

1. 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. The 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.

2. Special Conditions for Use Statement(s):

   For prescription use only.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   BD MAX System, K111860

2. Comparison with Predicate Device:

Similarities		
Item	**New Device: revogene instrument (K170558)**	**Predicate Device: BD Max System (K111860)**
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. The 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.	The BD MAX System is intended for *in vitro* diagnostic (IVD) use in performing FDA cleared or approved nucleic acid testing in clinical laboratories. The BD MAX System is capable of automated extraction and purification of nucleic acids from multiple specimen types as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR.
Sample Preparation Method	Automated cell lysis, DNA amplification, and detection of targets	Same

Similarities		
Item	**New Device: revogene instrument (K170558)**	**Predicate Device: BD Max System (K111860)**
Assay Format	Amplification: Real Time PCR Detection: Fluorgenic	Same
Interpretation of Test Results	Automated (Diagnostic software)	Same

Differences		
Item	**New Device: revogene instrument (K170558)**	**Predicate Device: BD Max System (K111860)**
DNA Purification	No purification. Lysis of cells, specimen dilution before PCR	Yes. Bound to magnetic beads, washed and released for subsequent testing
Assay Cartridge	• Single Use • One sample per PIE	• Can be used twice • Up to 24 samples per cartridge
Fluorescence Channels	4 channels	6 channels
Software	Software resides on the revogene instrument	Software resides on an all-in-one computer

I. Special Control/Guidance Document Referenced (if applicable):

- European Commission. EN 61326-1:2013: Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements. February 2013
- Food and Drug Administration. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; Guidance for Industry and Food and Drug Administration Staff. October 2, 2014.
- Food and Drug Administration. Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. May 11, 2005.
- Food and Drug Administration. Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software. January 14, 2005.
- Food and Drug Administration. Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices. September 9, 1999.
- International Electrotechnical Commission. IEC 61010-1:2010: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.

J. Performance Characteristics*:*

1. Analytical Performance:

   Performance for the revogene instrument was established in the clearance of the assay, GenePOC GBS LB Assay (K170557). All analytical and clinical testing for K170557 was performed with the revogene (software versions V2.5.2 and V3.0.12) and the GBS-specific assay definition file.

   a. Accuracy:

   See K170557

   b. Precision/Reproducibility:

   See K170557

   c. Linearity:

   See K170557

   d. Carryover:

   See K170557

   e. Interfering Substances:

   See K170557

2. Clinical Performance:

   See K170557

3. Other Supportive Instrument Performance Data Not Covered Above:

   Not Applicable

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

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