DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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GENMARK DIAGNOSTICS, INCORPORATED
ALAN MADERAZO, Ph.D., RAC
VP OF QUALITY, REGULATORY & CLINICAL AFFAIRS
5964 La PLACE COURT
CARLSBAD CA 92008

June 9, 2017

Re: K163652
Trade/Device Name: ePlex Instrument
Regulation Number: 21 CFR 862.2570
Regulation Name: Instrumentation for clinical multiplex test systems
Regulatory Class: II
Product Code: NSU
Dated: May 8, 2017
Received: May 9, 2017

Dear Dr. Maderazo:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Stephen J. Lovell -S for

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163652

Device Name
ePlex® Instrument

Indications for Use *(Describe)*
The ePlex Instrument is an automated in vitro diagnostic (IVD) device designed to perform multiplexed nucleic acid tests for the simultaneous detection and identification of nucleic acid targets by processing single-use cartridges developed and manufactured by GenMark Diagnostics, Inc.

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.

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510(k) Summary

Summary of Information to Support Substantial Equivalence to Predicate Device

Submitter Information

Submitter: GenMark Diagnostics, Incorporated
5964 La Place Court
Carlsbad, CA 92008

Manufacturer: GenMark Diagnostics, Incorporated
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Date Prepared: December 21, 2016

Name of Device and Classification

Product Name: ePlex® Instrument

Device Classification: 862.2570, Instrumentation for clinical multiplex test systems, Class II

Product Code: NSU, Instrumentation for Clinical Multiplex Test Systems.

Predicate Device

Predicate: BioFire Diagnostics FilmArray 2.0

Device Description

The ePlex® Instrument is used to run single-use assay cartridges that incorporate digital microfluidics and GenMark's eSensor® detection technology (used by products that are currently FDA-cleared; K073720 and K090901) to automate all aspects of nucleic acid testing. The ePlex Instrument is designed to: provide a nucleic acid amplification testing solution directly from various sample types, provide random access testing capability, and require minimal operator interaction.

The ePlex Instrument includes the following components:

- **Base:** A touchscreen graphical user interface (GUI) powered by a PC with a Windows Operating System 7. The base communicates with the bays to transfer data. The instrument software installed on the ePlex base processes the raw data generated by the individual bays and determines the test result.
- **Tower:** A chassis housing six bays. ePlex is scalable from one to four towers connected to either side of the base.
- **Bay:** 6 bays are housed in each tower. Each bay will accept cartridges independent of the testing status of the other bays allowing for random access testing. Each bay has an Ethernet port for communication with the base unit to receive user inputs and deliver test data to the ePlex Instrument software.

The touchscreen graphical user interface (GUI) is flanked on either side by a tower with six bays containing a slot for the cartridge and an LED to indicate bay status (in-use or available for use). The instrument is designed to be scalable with configurations to accommodate a single tower with 6 bays or up to four towers with 24 bays.

The ePlex system is used to run multiplex microarray-based assays developed by GenMark. This type of assay is based on the principles of competitive nucleic acid hybridization using a sandwich assay format, wherein a single-stranded target binds concurrently to a sequence-specific solution-phase signal probe and a solid-phase electrode-bound capture probe. The test employs nucleic acid extraction, target amplification via polymerase chain reaction (PCR) or reverse transcription PCR (RT-PCR) and hybridization of target DNA. In the process, the double-stranded PCR amplicons are digested with exonuclease to generate single-stranded DNA suitable for hybridization.

Nucleic acid extraction from biological samples occurs within the cartridge via cell lysis, nucleic acid capture onto magnetic beads, and release for amplification. The nucleic acid extraction is processed through microfluidic liquid handling. Once the nucleic acid targets are captured and inhibitors are washed away, the magnetic particles are delivered to the electrowetting environment on the printed circuit board (PCB) and the targets are eluted from the particles and amplified.

During hybridization, the single-stranded target DNA binds to a complementary, single-stranded capture probe immobilized on the working gold electrode surface. Single-stranded signal probes (labeled with electrochemically active ferrocenes) bind to specific target sequence / region adjacent to the capture probe. Simultaneous hybridization of target to signal probes and capture probe is detected by alternating current voltammetry (ACV). Each working electrode on the array contains specific capture probes, and sequential analysis of each electrode allows detection of multiple analyte targets.

Intended Use/Indications for Use

The ePlex Instrument is an automated *in vitro* diagnostic (IVD) device designed to perform multiplexed nucleic acid tests for the simultaneous detection and identification of nucleic acid targets by processing single-use cartridges developed and manufactured by GenMark Diagnostics, Inc.

Summary of Technological Characteristics of the Device Compared to the Predicate Device

The GenMark ePlex Instrument ("Subject Device") and the legally marketed device, BioFire FilmArray 2.0 ("Predicate Device") are described below:

Characteristic	Proposed Device	Predicate Device
Product Name	ePlex Instrument	FilmArray 2.0
Manufacturer	GenMark Diagnostics	BioFire Diagnostics
Regulation	862.2570 Instrumentation for clinical multiplex test systems	862.2570 Instrumentation for clinical multiplex test systems
Product Code	NSU: Instrumentation for Clinical Multiplex Test Systems	NSU: Instrumentation for Clinical Multiplex Test Systems
Device Class	Class II	Class II

Characteristic	Proposed Device	Predicate Device
Intended Use	The ePlex Instrument is an automated *in vitro* diagnostic (IVD) device designed to perform multiplexed nucleic acid tests for the simultaneous detection and identification of nucleic acid targets by processing single-use cartridges developed and manufactured by GenMark Diagnostics, Inc.	The FilmArray 2.0 is an automated in vitro diagnostic (IVD) device designed for use with FilmArray panels. The FilmArray 2.0 is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray 2.0 instrument interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The software automatically determines the results and provides a test report. The FilmArray 2.0 is composed of one to eight instruments connected to a computer running FilmArray 2.0 software, which controls the function of each instrument and collects, analyzes, and stores data generated by each instrument.
Assays	For use with FDA cleared GenMark developed panels including Respiratory Panel (RP).	For use with FDA cleared FilmArray panels: Respiratory Panel (RP) Blood Culture Identification (BCID) Panel Gastrointestinal (GI) Panel
Protocol Processing Steps	Cell disruption, nucleic acid extraction, RT-PCR, single stranding and signal detection	Cell disruption, nucleic acid extraction, PCR1 thermocycling, PCR2 thermocycling, DNA melt and signal detection.
Time to result	Approximately 90 minutes (depends on ePlex assay cartridge)	Approximately 1 hour per sample
Technological Principles	Multiplex nucleic acid amplification (including reverse transcription as appropriate) utilizing GenMark proprietary electrowetting technology, followed by detection of analyte targets utilizing GenMark proprietary eSensor® technology.	Nested multiplex nucleic acid amplification (including reverse transcription as appropriate) followed by high-resolution melting analysis to confirm the identity of the amplified product.
Required Accessory	GenMark ePlex Cartridge (aka "consumable" or "assay cartridge"), and barcode scanner	FilmArray Reagent Pouch
Sample Preparation Method	Minimal sample processing and hands-on time.	Minimal sample processing and hands-on time.
Test Interpretation	Automated test interpretation and report generation. User cannot access	Automated test interpretation and report generation. User cannot access raw data. Report can be printed.

Characteristic	Proposed Device	Predicate Device
and Results Reporting	raw data. Report can be printed, exported or sent to an LIS.	
User Interface	Touch-screen base unit with integrated PC on a Windows operating system.	FilmArray unit(s) plugged into a standalone PC operated on a Windows operating system.
User Complexity	Moderate	Moderate
Detection Procedure	Cyclic voltammetry on custom PCB	Complimentary metal-oxide semiconductor (CMOS) camera Hard-coated filters.
Detection Chemistries	Complimentary nucleic acid binding with ferrocene labeled probes	Melt curve analysis. Fluorescent imaging of PCR reactions.
Instrument-Software Communication	Communication travels via Ethernet cable/port.	Communication travels via Ethernet cable/port. Communication for multiple instruments mediated by a multi-port switch.
Device Configuration	A base unit containing an integrated PC; with onscreen key board and touch screen operation, and detachable barcode scanner and magnetic arm rest. Designed to support external keyboard and mouse. System is configurable with 1 to 4 towers; each tower contains 6 bays. Towers are attached to the left and right sides of the base, a maximum of 2 towers may be attached to each side. Printer provided with System and optional Universal Power Supply (UPS) offered. Each bay has single-sample test capacity. Random-access multi-sample test capacity per system.	Up to eight FilmArray 2.0 instruments to one computer with mouse, barcode scanner and pouch loading station. Single-sample test capacity per instrument with random-access multi-sample test capacity per system. Printer Provided with System. Interlocking two-instrument racks available to stack instruments and reduce system footprint. (Optional) Instrument held at 0° angle when no rack is used. Instrument held at 15° angle on the rack.

Analysis of the similarities and differences indicate that the devices are substantially equivalent in their intended uses/indications for use, and are generally the same regarding user process, ease of use and general operator protocol. Comparison of technological similarities and differences between the proposed device and the predicate do not raise new or different questions of safety and effectiveness, and therefore render the proposed device as substantially equivalent to the predicate device. Comparison of device performance characteristics will be included in each respective GenMark assay 510(k).

Summary of Performance Data

Performance of the ePlex Instrument was evaluated in a reproducibility study using the GenMark ePlex Respiratory Pathogen (RP) Panel. GenMark will submit a traditional 510(k) for the ePlex RP Panel that will be used with the ePlex Instrument. Complete non-clinical and clinical performance data will be included in the traditional 510(k) for the ePlex RP Panel.

The reproducibility study utilized samples prepared as a panel at moderate (3x LoD), low (1x LoD) and negative. The study was conducted at three separate testing sites with different ePlex instruments, by multiple operators performing runs over several days. Run validity, agreement, and variability were analyzed. Acceptance criteria were established in advance of conducting the study and all acceptance criteria were met.