

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

**A. 510(k) Number:**

k163652

**B. Purpose for Submission:**

Clearance of a new instrument

**C. Manufacturer and Instrument Name:**

GenMark Diagnostics, Inc.  
ePlex Instrument

**D. Type of Test or Tests Performed:**

Nucleic Acid Amplification Testing

**E. System Descriptions:**

1. Device Description:

The ePlex Instrument is a clinical multiplex test system that uses single-use assay cartridges that incorporate digital microfluidics and GenMark's eSensor detection technology to automate all aspects of nucleic acid testing. The instrument system is used with specific IVD assays to measure multiple analytes. The ePlex Instrument is for in vitro diagnostic use by trained laboratory professionals in a controlled laboratory environment and is not intended for patient contact.

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. 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.

2. Principles of Operation:

Assays developed for use on this system are based on 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.

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:

Barcode scanner, manual entry, or LIS pending test orders download.

5. Specimen Sampling and Handling:

Samples are manually prepared according to assay manufacturer's instructions and are then manually introduced into individual reagent cartridges.

6. Calibration:

User calibration not required. Each reagent cartridge contains an internal control.

7. Quality Control:

Each RP Panel cartridge includes internal controls that monitor performance of each step of the testing process. A DNA control verifies extraction, amplification and detection of DNA targets, and RNA controls verify amplification and detection of RNA targets.

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

2. Classification:

Class II

3. Product code:

NSU

4. Panel:

Clinical Chemistry (75)

**G. Intended Use:**

1. Indication 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.

2. Special Conditions for Use Statement(s):

Not Applicable

**H. Substantial Equivalence Information:**1. Predicate Device Name(s) and 510(k) numbers:

FilmArray 2.0 System, BioFire Diagnostics, LLC  
K143178

2. Comparison with Predicate Device:

<b>Similarities</b>		
<b>Characteristic</b>	<b>Proposed Device</b>	<b>Predicate Device</b>
<b>Product Name</b>	ePlex Instrument	FilmArray 2.0
<b>Manufacturer</b>	GenMark Diagnostics	BioFire Diagnostics
<b>Regulation</b>	862.2570 Instrumentation for clinical multiplex test systems	862.2570 Instrumentation for clinical multiplex test systems
<b>Product Code</b>	NSU: Instrumentation for Clinical Multiplex Test Systems	NSU: Instrumentation for Clinical Multiplex Test Systems
<b>Device Class</b>	Class II	Class II
<b>Intended Use</b>	The ePlex instrument is an automated <i>in vitro</i> 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 <i>in vitro</i> 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.
<b>Assays</b>	For use with FDA cleared GenMark developed panels including Respiratory Panel (RP).	For use with FDA cleared FilmArray panels including Respiratory Panel (RP), Blood Culture Identification (BCID) Panel, and Gastrointestinal (GI) Panel

<b>Similarities</b>		
<b>Characteristic</b>	<b>Proposed Device</b>	<b>Predicate Device</b>
<b>Protocol Processing Steps</b>	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.
<b>Time to result</b>	Approximately 90 minutes (depends on ePlex assay cartridge)	Approximately 1 hour
<b>Technological Principles</b>	Multiplex nucleic acid amplification (including reverse transcription as appropriate) utilizing proprietary electrowetting technology, followed by detection of analyte targets utilizing 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.
<b>Sample Preparation Method</b>	Minimal sample processing and hands-on time.	Minimal sample processing and hands-on time
<b>Test Interpretation and Results Reporting</b>	Automated test interpretation and report generation. User cannot access raw data. Report can be printed, exported or sent to an LIS.	Automated test interpretation and report generation. User cannot access raw data. Report can be printed.
<b>User Interface</b>	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.
<b>User Complexity</b>	Moderate	Moderate

<b>Differences</b>		
<b>Characteristic</b>	<b>Device</b>	<b>Predicate</b>
<b>Detection Procedure</b>	Cyclic voltammetry on custom PCB	Complimentary metal-oxide semiconductor (CMOS) camera Hard-coated filters.
<b>Device Configuration</b>	A base unit containing an integrated PC; with onscreen key board and touch screen operation, and detachable barcode scanner and magnetic arm rest. 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.	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

Differences		
Characteristic	Device	Predicate
	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.	is used. Instrument held at 15° angle on the rack.

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

Class II Special Controls Guidance Document: *Instrumentation for Clinical Multiplex Test Systems - Guidance for Industry and FDA Staff*, March 10, 2005

**J. Performance Characteristics:**

1. Analytical Performance:

a. *Accuracy:*

See k163636

b. *Precision/Reproducibility:*

See k163636

c. *Linearity:*

See k163636

d. *Carryover:*

See k163636

e. *Interfering Substances:*

See k163636

2. 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:**

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