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

A. 510(k) Number:
k073506

B. Purpose for Submission:
New submission

C. Manufacturer and Instrument Name:
Luminex LX 100/200 Instrument

D. Type of Test or Tests performed:
Multiplex protein and nucleic acid testing

E. System Descriptions:

1. Device Description:
   LUMINEX 100/200 SYSTEM

   The Luminex 100/200 System is a compact analyzer that performs up to 100 bioassays simultaneously, using a single drop of fluid therefore requiring very small patient samples. This system utilizes software version IS 2.3 of the xMAP technology operating system.

   LUMINEX XYP

   The Luminex XYP platform (Luminex XYP) compliments the Luminex 100/200 System by automating the sequential positioning of each well of the microtiter plate.

   LUMINEX SD

   The Luminex Sheath Delivery System (Luminex SD) allows the user to run samples continuously in a low or high throughput mode unattended.

   IS 2.3 SOFTWARE

   The Luminex LX100/200 system utilizes software version IS 2.3 of the xMAP technology operating system. This software allows for both protein and nucleic acid testing utilizing the Luminex platform.

   CONSUMABLES

STANDARD MICROSPHERES

xMAP microspheres are internally labeled with fluorescent dyes and are carboxylated.

REAGENTS

xMAP CLASSIFICATION CALIBRATOR MICROSPHERES

xMAP Calibrator Microspheres, Classification (CAL1) and Reporter (CAL2), are polystyrene microspheres that are internally labeled with fluorescent dyes. They serve as system calibrators for Luminex xMAP technology based detectors and are intended to normalize the settings for both the classification channel (CL1, CL2), the doublet discriminator channel (DD), and the reporter channel (RP1). The product is not intended to be used in place of the assay calibrators that are required to verify the proper function of a given assay.

xMAP CLASSIFICATION CONTROL MICROSPHERES

xMAP Control Microspheres, Classification (CON1) and Reporter (CON2), are polystyrene microspheres that are internally labeled with fluorescent dyes. The control microspheres are intended to verify the calibration and optical integrity for the Luminex 100/200 System. Classification Control Microspheres verify both classification channels and the doublet discriminator channel (DD). Reporter Control Microspheres verify the reporter channel. The product is not intended to be used in place of the assay controls that are required to verify the proper function of a given assay.

xMAP SHEATH FLUID

Sheath fluid is the delivery medium of the sample to the optics component. The analysis sample is acquired using a Sample Probe from a 96-well microtiter plate via the Luminex XYP instrument and injected into the base of the cuvette.

2. Principles of Operation:

Luminex's xMAP technology is built on flow cytometry, microspheres, lasers, digital signal processing and traditional chemistry. Systems using xMAP technology perform discrete bioassays on the surface of the color coated beads know as microspheres, which are then read in a compact analyzer. The analyzer reads multiplexed assay results by identifying color differences between beads as well as the presence or absence of a fluorescent reporter marker.

Luminex's xMAP technology is based on flow cell fluorometry. The fluidics, optics, robotics, temperature control, software, and xMAP microspheres work together to enable simultaneous analysis of up to 100 analytes in a single test sample. Assay analysis requiring temperature control is provided through the Luminex XYP instrument heater block.

There are two fluidics paths in the Luminex 100/200 analyzer. The first path involves a syringe-driven mechanism that controls the sample uptake. This mechanism permits small sample uptake volumes from small reaction volumes. The syringe-driven system transports a specified volume of sample from a sample container to the cuvette. The sample is injected into the cuvette at a steady rate for analysis. Following analysis, the sample path is automatically purged with sheath buffer by the second fluidics path. This process removes residual sample within the tubing, valves, and probe. The second fluidics path is driven by positive air pressure and supplies sheath fluid to the cuvette and sample path.

Sheath fluid is the delivery medium of the sample to the optics component. The analysis sample is acquired using a Sample Probe from a 96-well microtiter plate via the Luminex XYP instrument and injected into the base of the cuvette. The sample then passes through with sheath fluid at a reduced rate resulting in a narrow sample core to ensure that each microsphere is illuminated individually. The sample injection rate is such that the xMAP microspheres are introduced to the optics path as a series of single events. The optics assembly consists of two lasers. One laser excites the dye mixture inside the xMAP microspheres and the second laser excites the fluorophere bound to the surface of the xMAP microspheres. Avalanche photo diode detectors measure the excitation emission intensities of the color coding classification dye mixtures inside the xMAP microspheres and a photomultiplier tube detects the excitation emission intensity of the reporter molecule bound to the surface of the xMAP microspheres. High speed digital signal processors and computer algorithms provide analysis of the xMAP microspheres as they are processed through the Luminex 100/200 analyzer. Results of the analyses are processed and provided in a report format.

3. Modes of Operation:

   Automatic - sequential positioning of each well of a 96 well microtiter plate

4. Specimen Identification:
   Barcode reader entry of sample IDs

5. Specimen Sampling and Handling:

Samples are manually prepared according assay manufacturers' suggestions and transferred to 96-well microtiter plate for analysis.

6. Calibration:
   xMAP Calibrator Microspheres, Classification (CAL1) and Reporter (CAL2) serve as system calibrators for Luminex xMAP technology based detectors and are intended to normalize the settings for both the classification channel (CL1, CL2), the doublet discriminator channel (DD), and the reporter channel (RP1). They are not intended to be used as calibrators for a given assay.

7. Quality Control:
   xMAP Control Microspheres, Classification (CON1) and Reporter (CON2) are intended to verify the calibration and optical integrity for the Luminex 100/200 System. Classification Control Microspheres verify both classification channels and the doublet discriminator channel (DD). Reporter Control Microspheres verify the reporter channel. They are not intended to be used as controls for a given assay.

8. Software:
   FDA has reviewed the applicant's Hazard Analysis and software Documentation: Yes___X__ or No _____

F. Regulatory Information:

1. Regulation Section:
   21CFR §862.2570 - Instrumentation for clinical multiplex test systems.
   Class II
2. Product Code:
   NSU
3. Panel:
   Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:
   The Luminex LX 100/200 Instrument is a clinical multiplex test system intended to measure and sort multiple signals generated in an In Vitro Diagnostic assay from a clinical sample. This instrumentation is used with a specific assay to measure multiple similar analytes that establish a single indicator to aid in diagnosis. The device includes a signal reader unit, raw data storage mechanisms, data acquisition software and software to process detected signals.
2. Special Condition for use Statement(s):
   For professional use only

H. Substantial Equivalence Information:

1. Predicate device name(s)and 510(k) numbers:
   Affymetrix Genechip Microarray Instrumentation System
   k042279

2. Comparison with Predicate Device:

Topic	**Luminex 100/200 IS System** 510(k) Number: k073506	**Affymetrix GeneChip Microarray Instrument System** 510(k) Number: k042279
Intended use	The Luminex LX 100/200 Instrument is a clinical multiplex test system intended to measure and sort multiple signals generated in an In Vitro Diagnostic assay from a clinical sample. This instrumentation is used with a specific assay to measure multiple similar analytes that establish a single indicator to aid in diagnosis. The device includes a signal reader unit, raw data storage mechanisms, data acquisition software and software to process detected signals.	The Affymetrix GeneChip® Microarray Instrumentation System consisting of GeneChip® 3000Dx scanner with autoloader, FS450Dx fluidics station and GCOSDx software is intended to measure fluorescence signals of labeled DNA target hybridized to GeneChip® arrays for use with separately cleared GeneChip microarray assays
Assays used to establish instrument performance	• Luminex, Id-Tag Respiratory Viral Panel - k063765, • Inova, Quanta Plex Celiac IgA Profile - k063818 • Inova, Quanta Plex ANCA Profile k050715	• Roche, Amplichip CYP450 Test - K042259
System Description	**See Device Description section above.**	**Affymetrix GeneChip Microarray Instrumentation System** The Affymetrix GeneChip Microarray Instrumentation System is designed to work with microarrays based on Affymetrix GeneChip ® technology. Device Features Controlled by Software. The GeneChip® Operating Software (GCOSDx) provides the interface between the user and the instruments. GCOSDx controls the FS450Dx, GCS3000Dx and the AutoLoaderDx. GCOSDx may also be used to monitor the operations being performed by each instrument. GCOSDx controls the fluidics station using fluidics scripts specific to the assay being performed. Fluidics scripts are written to a directory specified during GCOSDx installation. GCOSDx aids and controls scanner movement and image capture including grid alignment. GCOSDx displays a picture of the scan image in an image window on the computer workstation. The software represents the fluorescence intensity values from each pixel on the array in a grayscale or pseudocolor mode. This image is saved as a ".dat" file format. GCOSDx

Topic	Luminex 100/200 IS System 510(k) Number: k073506	Affymetrix GeneChip Microarray Instrument System 510(k) Number: k042279
		then uses an alignment algorithm to superimpose a grid on the image to delineate probe cells. The alignment algorithm uses a checkerboard image of control probes, located at the corners of the probe array to superimpose the grid on the scanned image. GCOSDx generates cell intensity data from the image data. The cell analysis algorithm analyzes the image data and computes a single intensity value for each probe cell on the array. This data is saved as a ".cel" file. It is the ".cel" file that is handed to the assay specific software for final data analysis and result reporting. **FS450Dx Fluidics Station** The FS450Dx (Fluidics Station) is an instrument consisting of four modules installed in a single Station or housing. Each module holds a single GeneChip microarray and performs the functions required for hybridization, washing, and staining of that array. Up to 8 stations communicate to a workstation. Each module contains controls the addition of target and staining fluids to the array cartridge and subsequent washing of the array. The module contains a pump, valve, thermo-electric system, and LCD that are controlled by scripts selected by the system operator and automatically downloaded to each module, then stored in the module's electronic memory. **GCS3000Dx Scanner** The GCC3000Dx Scanner is a wide-field, epifluorescent, confocal, scanning laser microscope which scans the chip after the staining process performed by the Fluidics Station. Array cartridges are loaded into the scanner by an automatic handler (the Autoloader) prior to scanning, and returned to the handler after scanning is complete.

Topic	Luminex 100/200 IS System 510(k) Number: k073506	Affymetrix GeneChip Microarray Instrument System 510(k) Number: k042279
		GCOSDx Software The GeneChip® Operating Software (GCOSDx) provides the interface between the user and instrument systems. It is the software that provides instrument control and the application for processing arrays and data collection. Upon completion of scanning of the array, data is passed through GCOSDx to the assay specific software component that contains the algorithms and reporting functions to produce a clinical result.
Calibration	System calibration is performed on a monthly basis as part of regularly scheduled maintenance. This is independent of assay calibration.	No user calibration required.

I. Standard/Guidance Document Referenced (if applicable):

Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems

J. Performance Characteristics:

Performance for the Luminex LX 100/200 Instrument was established in the Luminex, Id-Tag Respiratory Viral Panel - k063765, the Inova, Quanta Plex Celiac IgA Profile - k063818 and the Inova, Quanta Plex ANCA Profile k050715 submissions.

1. Analytical Performance:
    a. *Accuracy:*
    Subject of k063765, k063818 and k050715
    b. *Precision/Reproducibility:*
    Subject of k063765, k063818 and k050715
    c. *Linearity:*
    Subject of k063765, k063818 and k050715
    d. *Carryover:*
    Subject of k063765, k063818 and k050715
    e. *Interfering Substances:*
    Subject of k063765, k063818 and k050715

2. Other Supportive Instrument Performance Data Not Covered Above:
    None

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.