DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 9, 2013

Luminex, Inc.
c/o Oliver Meek
Vice President, Quality Assurance and Regulatory Affairs
12212 Technology Blvd.
AUSTIN, TX 78727

Re: k121399
Trade/Device Name: FLEXMAP 3D® Instrument System with Luminex® xPONENT 4.0 SP1 Software; FLEXMAP 3D® IVD Calibration Kit, and FLEXMAP 3D® IVD Performance Verification Kit
Regulation Number: 21 CFR 862.2570
Regulation Name: Instrumentation for Clinical Multiplex Test Systems
Regulatory Class: Class II
Product Code: NSU
Dated: December 7, 2012
Received: December 10, 2012

Dear Mr. Oliver Meek:

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.

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 Part 801); 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 regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Reena Philip -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k121399

Device Name: Luminex® FLEXMAP 3D®

The Luminex® FLEXMAP 3D® system with xPONENT® software version 4.0 SP1 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 intended for use with specific IVD cleared or approved assays citing its use, to measure multiple similar analytes that establish a single indicator to aid in diagnosis.

Prescription Use X AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics Evaluation and Safety (OIVD)

Karen E. Bijwaard -S
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Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k121399