BIOMÉRIEUX

JUL – 6 2010

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K093383.

Name of device

NucliSENS EasyQ® System, including the following components:

Instrumentation and Software

NucliSENS EasyQ® Analyzer
NucliSENS EasyQ® Director Software 2.6
NucliSENS EasyQ® assay protocol software
- *included in the NucliSENS EasyQ® assay kit for the specific assay used*

NucliSENS EasyQ® Incubator II
NucliSENS EasyQ® Computer and peripherals (monitor, printer, keyboard, mouse)
NucliSENS miniMAG®

Reference is made to the performance of the system as previously cleared for the ***NucliSENS EasyQ® Enterovirus v1.1 Assay*** (K063261).

Classification

Product code: OOI Real Time Nucleic Acid Amplification System
Regulation: 862.2570 Instrumentation for clinical multiplex test systems
Device Class: Class II

Device to which equivalence is claimed

The device, which is the subject of this submission, is claimed equivalent to the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with the SDS Software version 1.4 (K082562).

Intended Use of the Device

In vitro diagnostic medical device.

The ***NucliSENS EasyQ Analyzer*** and the accompanying ***NucliSENS EasyQ Director*** software are intended for *in vitro* diagnostic use in conjunction with FDA-cleared or approved ***NucliSENS*** assay protocols. The user shall be a properly trained laboratory technician familiar with performing nucleic acid assays. The analyzer is intended to measure fluorescent readings from molecular beacon probes binding to amplified RNA or DNA in samples containing ***NucliSENS EasyQ*** assay reagents while controlling the temperature of the samples. The ***NucliSENS EasyQ Director*** software is intended to control instrument operations and organize the assays to be performed. In addition, the software is intended to automatically calculate results for each test request based on raw measurement data, the data reduction algorithm specified for the assay, and the batch parameters of the reagents used for the test.

Description of the Device

The ***NucliSENS EasyQ System*** includes principally the instrument, ***NucliSENS EasyQ® Analyzer***, and the software, consisting of ***NucliSENS EasyQ® Director Software 2.6*** used in combination with assay-

specific ***NucliSENS EasyQ®*** assay protocols. The system also requires use of the instrument, ***NucliSENS EasyQ® Incubator II***.

The ***NucliSENS EasyQ® Analyzer*** (Analyzer) is an automated, temperature-controlled fluorescence analyzer instrument designed for batch processing of up to 96 samples per run. Amplification of nucleic acid targets is detected by means of sequence-specific probes which each fluoresce upon binding of the probe to its target. The Analyzer contains a plate carrier, which is designed to keep temperature constant at the required assay temperature. The Analyzer is a specially designed fluorescent reader using an optical system based on direct and focused illumination, designed to prevent crosstalk. Specific filters are used to select the appropriate wavelength for both excitation and emission of the molecular beacons used in the assay specified for each test. The filter selection is controlled by the attached PC and is a function of the assay protocol applied to a specified test.

Once sample tube strips have been loaded into plate carrier block of the Analyzer, the instrument moves the first tube into position over the light source. The Analyzer then directs the light source upward through the bottom of the sample tube. The light causes the molecular beacons (in the assay reagent mixture) to emit light. Through the use of a mirror, the emitted light is directed through an optical filter to a photomultiplier tube where the fluorescence reading is taken. The next sample is then moved into position and the process is repeated. The intensity of the emitted light is measured for each sample and the process is repeated for each test as the run progresses, generating a series of data points for each sample that form fluorescence curves.

The Analyzer is used in combination with ***NucliSENS EasyQ® Director software*** (Director software) and assay-specific ***EasyQ® assay protocol software*** (assay protocols), loaded on a ***NucliSENS EasyQ® computer*** with a keyboard and screen interface. The Director Software is used for instrument control and data collection. In combination with assay-specific "assay protocols", the Director Software also performs automated result calculation and reporting based on the analysis of real-time fluorescence signal curves measured by the Analyzer. Results may be qualitative or quantitative, depending on the design of the assay and the assay protocol. Results available to the operator include both the qualitative or quantitative test result and the graph of the fluorescence data points (data curves).

The device which is the subject of this submission is largely unchanged from the ***NucliSENS EasyQ System*** used in conjunction with the assay ***NucliSENS EasyQ® Enterovirus v1.1,*** which received 510(k) clearance from FDA (K063261) on 23-Jun-2008.

The following assay components and characteristics are unchanged from the system as cleared in K063261:

- intended use and indications for use
- test principle
- modes of operation
- reagents
- controls
- performance characteristics
- EasyQ Analyzer instrument
- MiniMAG instrument
- EasyQ Enterovirus v1.1 assay protocol software
- Instructions for Use, except administrative changes as needed to reference current versions of software and instrumentation (listed below)

Changes to the assay system are as follows:

- a cleared instrument is being replaced with another instrument of equivalent performance (EasyQ Incubator -> EasyQ Incubator II)
- a key software component is being upgraded (Director 2.5 -> 2.6)

- the software upgrade enhances the assay's ease of use by enabling sorting of test requests according to several key test parameters (sample ID, priority, sample volume, etc.) and by allowing the operator to order a retest from the original sample
- use of the upgraded software in connection with the EasyQ Enterovirus v1.1 assay has been validated by internal in-silico testing using a panel of input data selected from prior test results, and representative of all foreseeable classes of test specimens

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

BIOMÉRIEUX
c/o Jocelyn Jennings, R.A.C.
Senior Manager, Regulatory Affairs
100 Rodolphe Street
Durham, NC 27712

JUL 0 6 2010

Re: k093383
Trade/Device Name: NucliSENS EasyQ® System
Regulation Number: 21CFR §862.2570
Regulation Name: Instrumentation for clinical multiplex test systems
Regulatory Class: Class II
Product Code: OOI
Dated: June 23, 2010
Received: June 28, 2010

Dear Ms. Jennings:

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 class II (Special Controls), it may be subject to such 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. This letter will allow you to begin marketing your device as described in your Section

510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety 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,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K093383

Device Name: ***NucliSENS EasyQ® System***, including the following components:

Instrumentation and Software

NucliSENS EasyQ® Analyzer
NucliSENS EasyQ® Director Software 2.6
NucliSENS EasyQ® assay protocol software
- *included in the NucliSENS EasyQ® assay kit for the specific assay used*

NucliSENS EasyQ® Incubator II
NucliSENS EasyQ® Computer and peripherals (monitor, printer, keyboard, mouse)
NucliSENS miniMAG®

Indications For Use: The ***NucliSENS EasyQ Analyzer*** and the accompanying ***NucliSENS EasyQ Director*** software are intended for *in vitro* diagnostic use in conjunction with FDA-cleared or approved ***NucliSENS*** assay protocols. The user shall be a properly trained laboratory technician familiar with performing nucleic acid assays. The analyzer is intended to measure fluorescent readings from molecular beacon probes binding to amplified RNA or DNA in samples containing ***NucliSENS EasyQ*** assay reagents while controlling the temperature of the samples. The ***NucliSENS EasyQ Director*** software is intended to control instrument operations and organize the assays to be performed. In addition, the software is intended to automatically calculate results for each test request based on raw measurement data, the data reduction algorithm specified for the assay, and the batch parameters of the reagents used for the test.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Device Evaluation and Safety

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k093383