K082562

Applied Biosystems

SEP 3 0 2008

510(k) Summary

Summary of Safety and Effectiveness

Submitter Information:

Submitter: Applied Biosystems
850 Lincoln Centre Drive
Foster City, CA 94404

Contact: John D'Angelo
Vice President of Regulatory and Quality Affairs
650-554-2005
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Name of Device and Classification:

Name: Applied Biosystems 7500 Fast Dx

Classification: Class II

Predicate Devices:

Applied Biosystems is submitting this application under 21 CFR Part 862.2570 Instrumentation for clinical multiplex test systems, Class II. The predicate device is the Affymetrix GeneChip Microarray instrument System.

Description of Device:

The AB 7500 Fast Dx RT-PCR instrument integrates a thermal cycler, a fluorimeter and application specific software. The instrument houses the thermal cycler and the

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fluorimeter, while the application software is run on a PC that is attached to the instrument. Samples are placed in a tube strip or 96-well low-head space plate that is moved to a Peltier-based thermal block and positioned relative to the optics using a tray loading mechanism.

Excitation for all samples is provided by a halogen tungsten white source that passes through 5 switchable excitation filters prior to reaching the sample. Fluorescence emission is then detected through 5 color emissions filter wheel to a charge coupled device (CCD) camera. The instrument is designed to complete quantitative RT-PCR runs in about 40 minutes.

The Sequence Detection Software (SDS) version 1.4 for the 7500 Fast Dx Instrument is used for instrument control, data collection and data analysis. The software can measure cycle-by-cycle real-time signals from the sample. The software provides a variety of tools to help the user analyze the data extracted from the samples. The software also provides lamp-life monitoring and other instrument maintenance information. The software runs as an application on Windows XP platform. Changes to the Dx software are subject to change control in accordance with 21 CFR Part 820.40.

Intended Use / Indications for Use:

The Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with the SDS Software version 1.4 is a real-time nucleic acid amplification and detection system that measures nucleic acid signals from reverse transcribed RNA and converts them to comparative quantitative readouts using fluorescent detection of dual-labeled hydrolysis probes. The 7500 Fast Dx is to be used only by technologists trained in laboratory techniques, procedures and on use of the analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. John D'Angelo
Vice President of Regulatory Affairs
Applied Biosystems
850 Lincoln Centre Drive
Foster City, CA 94404

SEP 30 2008

Re: K082562
Trade/Device Name: Applied Biosystems 7500 Fast Dx
Regulation Number: 21 CFR 862. 2570
Regulation Name: Instrumentation for clinical multiplex test systems
Regulatory Class: Class II
Product Code: NSU
Dated: September 2, 2008
Received: September 4, 2008

Dear Mr. D'Angelo:

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 such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

Applied Biosystems

Indications for Use Statement

510(k) Number (if known): K082562

Device Name: Applied Biosystems 7500 Fast Dx

Indications For Use:

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Prescription Use X OR Over-The-Counter Use _____
(per 21 CFR 801.109)

Division Sign-Off

(Optional Format 1-2-96)

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k082562