K033734

DEC 17 2003

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
317-521-2386

Contact Person: Robert A. Gregg, PhD

Date Prepared: November 26, 2003

Device Name

Proprietary name: LightCycler Instrument Version 1.2

Common name: Automated analyzer for nucleic acid amplification and detection

Classification name: Analyzer, Chemistry, Micro, for clinical use.

Device Description

The LightCycler Instrument consists of a microvolume fluorimeter integrated with a thermal cycler. It combines rapid-cycler PCR in glass capillaries heated with hot-air with real-time fluorescence monitoring. The system is designed to reduce the time needed to achieve results from PCR and to enable the user to monitor the amplification of the PCR product simultaneously, in real-time and on-line.

The LightCycler instrument has been CE marked with regards to electromagnetic compatibility and electrical safety.

Further details about the LightCycler Instrument can be found in the LightCycler Operator's Manual.

Intended use

The LightCycler Instrument is a fully automated amplification and detection system for nucleic acids using fluorescence detection.
The LightCycler is intended to be used by laboratory professionals trained in laboratory techniques and on the use of the analyzer.

Substantial equivalence

The LightCycler Instrument Version 1.2 is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed COBAS TaqMan Analyzer K012966.

The LightCycler Instrument is a flexible benchtop analyzer that automates the amplification and detection steps of the Polymerase Chain Reaction (PCR). The principles of operation of the LightCycler are substantially equivalent to those used for the predicate, COBAS TaqMan Analyzer. Both analyzers perform various steps such as heating and measurement of light intensity. The primary operational components of both analyzers are the thermal cycler and the photometer.

Comparison to predicate device

The following tables compares the LightCycler with the predicate device, the COBAS TaqMan Analyzer

Similarities:

Feature	LightCycler	COBAS TaqMan Analyzer
Intended use	The LightCycler Instrument is a fully automated amplification and detection system for nucleic acids using fluorescence detection. The LightCycler is intended to be used by laboratory professionals trained in laboratory techniques and on the use of the Analyzer.	The COBAS TaqMan Analyzer is a fully automated amplification and detection system for nucleic acids using 5' nuclease technology. The COBAS TaqMan Analyzer is intended to be used by laboratory professionals trained in laboratory techniques and on the use of the Analyzer.
Primary operational components	Integrated thermocycler and microvolume fluorimeter for walkaway PCR amplification and detection	Same
Detection Procedure	Optical detection of stimulated fluorescence	Same
Specimen type	Purified nucleic acids	Same
Specimen Preparation	Performed off-line	Same
Temperature range	40 - 98 °C	Same
User interface	PC with instrument -specific software (LightCycler version 3.5 or higher)	PC with instrument -specific software (Amplilink Software version 3.0 or higher)

Differences

Feature	LightCycler	COBAS TaqMan Analyzer
Heating method thermal cycling	Hot air cycling with glass capillaries	Peltier device with sample block
Number of thermal cyclers	One	Four
Sample positions	32	96
Sample Size	10-20 uL in glass capillaries	100 uL in 200 uL K-tubes
Number of optical detection channels	Three with fixed wavelengths (530 nm, 640 nm, 710 nm)	Four with wavelength ranges 510-710 nm
Detection chemistry	Paired hybridization probes using fluorescence resonance energy transfer (FRET)	5' nuclease hydrolysis probes using FRET ('TaqMan technology')
Detection timing	Detection occurs at defined intervals during PCR cycle and can be viewed in real-time	Detection occurs only at end of each PCR cycle and can be viewed at completion of run
Absolute temperature accuracy	$\pm$ 0.4 °C	$\pm$ 1.5 °C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 17 2003

Robert A. Gregg, Ph.D
Director, Regulatory Submissions
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250

Re: k033734
Trade/Device Name: LightCycler Instrument Version 1.2
Regulation Number: 21 CFR 862.2170
Regulation Name: Analyzer, Chemistry, Micro, for clinical use
Regulatory Class: Class I
Product Code: JJF
Dated: November 26, 2003
Received: November 28, 2003

Dear Dr. Gregg:

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
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): N/A K033734

Device Name: LightCycler Instrument Version 1.2

Indications For Use:

The LightCycler Instrument is a fully automated amplification and detection system for nucleic acids using fluorescence detection.
The LightCycler is intended to be used by laboratory professionals trained in laboratory techniques and on the use of the analyzer.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033734