K102314

510(k) Summary
3M Integrated Cycler
Prepared Date: October 13, 2010

Applicant	Focus Diagnostics, Inc. 11331 Valley View Street Cypress, California 90630 USA
Establishment Registration No.	2023365
Contact Person	Tara Viviani tel 714.822.2115 fax 714.822.3898 tviviani@focusdx.com
Summary Date	October 13, 2010
Proprietary Name	3M Integrated Cycler
Generic Name	Thermocycler
Classification	Class II
Predicate Devices	Cepheid SmartCycler Dx system

OCT 2 9 2010

Intended Use

The Integrated Cycler and accompanying Studio Software are intended for in vitro diagnostic use in conjunction with legally marketed Simplexa™ reagent kits and assay protocols labeled for in vitro diagnostic use.

The Integrated Cycler is a rapid real-time Polymerase Chain Reaction (PCR) thermocycler used for identification of nucleic acid from prepared biological samples. The instrument utilizes disc media to contain and to process samples. The instrument uses real-time flourometric detection to identify targets within the sample wells. The instrument's operation parameters are controlled by the use of an external personal computer and associated software. This instrument is intended to be used by laboratory professionals trained in laboratory techniques and in a laboratory environment.

Device Description

The 3M Integrated Cycler is a rapid real-time Polymerase Chain Reaction thermocycler used for the identification of nucleic acid from prepared biological samples. The instrument utilizes disk media to contain and to process samples. The instrument uses real time flourometric detection to identify targets within the sample wells. The instrument is controlled by an external computer running the Integrated Cycler Studio Software.

Predicate Device Information

Trade Name / Method	510(k) submitter	510(k) number	Decision Date	Panel	Product Code(s)
SmartCycler Dx system	Cepheid	K062948	12/08/2006	(83) Microbiology	NJR (assay)

Item Name	Device Integrated Cycler	Predicate Cepheid SmartCycler Dx system
Similarities		
Intended Use	The Integrated Cycler and accompanying Studio Software are intended for in vitro	The Cepheid SmartCycler Dx System utilizes real-time polymerase chain reaction

Item Name	Device Integrated Cycler	Predicate Cepheid SmartCycler Dx system
	diagnostic use in conjunction with legally marketed Simplexa™ reagent kits and assay protocols labeled for in vitro diagnostic use. The Integrated Cycler is a rapid real-time Polymerase Chain Reaction (PCR) thermocycler used for identification of nucleic acid from prepared biological samples. The instrument utilizes disc media to contain and to process samples. The instrument uses real-time flourometric detection to identify targets within the sample wells. The instrument's operation parameters are controlled by the use of an external personal computer and associated software. This instrument is intended to be used by laboratory professionals trained in laboratory techniques and in a laboratory environment.	(PCR) for a unique gene-specific sequence amplification nucleic acids recovered from clinical samples and fluorogenic target specific hybridization for the detection of the amplified DNA.
Assay Methodology	PCR-based system for detecting the presence / absence of DNA or RNA in clinical specimens	PCR-based system for detecting the presence / absence of DNA or RNA in clinical specimens
Detection Techniques	Multiplex assay using different reporter dyes for each target.	Multiplex assay using different reporter dyes for each target.
Detection Channels	4 channels Excitation (nm) 475, 520 nm, 580 nm, 640 nm Emission (nm) 520 , 560 nm, 610, 682 nm	4 channels Excitation (nm) 450–495, 500–550, 565–590, 630–650 Emission (nm) 510–527, 565–590, 606–650, 670–750
Differences		
Sample Capacity	Up to 96 specimens and controls in a single run using the Universal Disc.	Up to 16 specimens and controls per modular unit. Up to 6 modules may be installed for a total of 96 specimens and controls
Sample Handling	96 well Universal Disc with Universal Disc Sealer	Individual Smart Tube and Smart Cap system.
Protocol Access	Assays using the same protocol parameters may be assayed on a single Universal Disc.	Up to 96 individual assay protocols may be randomly accessed.

Performance Characteristics

Reproducibility:
Reproducibility was assessed during the clearance of the assay (k100148) and will be addressed for each assay to be run on this system.

Limit of Detection
Limit of Detection was assessed during the clearance of the assay (k100148) and will be addressed for each assay to be run on this system.

Analytical Reactivity
Analytical Reactivity was assessed during the clearance of the assay (k100148) and will be addressed for each assay to be run on this system.

Cross-Reactivity
Cross-Reactivity was assessed during the clearance of the assay (k100148) and will be addressed for each assay to be run on this system.

Clinical Agreement
Clinical Agreement was assessed during the clearance of the assay (k100148) and will be addressed for each assay to be run on this system.

Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

OCT 29 2010

Focus Diagnostics Inc.
c/o Tara Viviani
Regulatory Affairs Project Manager
11331 Valley View St.
Cypress, CA 90630

Re: k102314

Trade/Device Name:	3M Integrated Cycler
Regulation Number:	21CFR §862.2570
Regulation Name:	Instrumentation for clinical multiplex test systems
Regulatory Class:	Class II
Product Code:	OOI
Dated:	August 13, 2010
Received:	August 16, 2010

Dear Ms. Viviani:

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,

Uwe Scherf for

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

510(k) Number (if known): K102314

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Device Name: 3M Integrated Cycler

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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 OF NEEDED)

Concurrence of CDRH, Office of InVitro Diagnostics (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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