FEB - 4 2009

510(k) Summary

CELL-DYN Emerald™ System

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: K081495

Submitted by	**Contact Person**
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Date Prepared: December 23, 2008

Proprietary Name: CELL-DYN Emerald™ System

Common Name: Automated Hematology Analyzer

Classification Name: Automated Differential Cell Counter (21 CFR 864.5220)

Predicate Device: Abbott CELL-DYN® 1800 System, K030513

Device Description:

The CELL-DYN Emerald System is a bench top analyzer consisting of the main analyzer with data module, display station, and printer. The main analyzer, data module, and display station are housed in a single chassis. The printer is a stand-alone module.

The CELL-DYN Emerald open sampler is equipped to aspirate blood from a collection tube that has been opened and is held under the open sample aspiration probe.

Intended Use

The CELL-DYN Emerald System is an automated hematology analyzer designed for in vitro diagnostic use in clinical laboratories.

Similarities and Differences

The CELL-DYN Emerald System and the CELL-DYN 1800 System are similar in that:

Both systems are bench top 3-part differential hematology with built-in monitors and data station.

Both systems analyze 16 parameters (measurands).

Both systems accept open specimens presented manually by the operator.

Both systems automatically aspirate the specimen and present it for automated processing.

Both systems use microprocessors for systems control, data acquisition, and data analysis.

Both systems provide RS232 interface to an on-line LIS.

Both systems provide Histograms, Dispersional Data Alerts, Suspect Parameter Messages, and Critical Limit Flagging.

Both systems use electrical impedance technology for counting and sizing cells.

Both systems use LED Hemoglobin analysis.

Both systems use a Cyanide-Free differential lyse reagent.

Both systems are capable of inputting specimen information from a bar code through a hand held bar code scanner and both systems use alphanumeric specimen ID's.

Both systems are capable of data output to a dot matrix or inkjet printer.

The CELL-DYN Emerald System and the CELL-DYN 1800 System are different in that:

The CELL-DYN Emerald analyzer is smaller and more compact than the CELL-DYN 1800.

The CELL-DYN Emerald System has a touch screen and built-in keypad while the CELL-DYN 1800 has an external keyboard.

The CELL-DYN Emerald System has two USB ports and one serial port while the CELL-DYN 1800 System has a floppy drive and serial port for printing and data storage options.

The CELL-DYN Emerald System uses different boards and microprocessors.

The CELL-DYN Emerald System has a password protection to secure software fields while the CELL-DYN 1800 does not have password protection.

The CELL-DYN Emerald Cleaner reagent contains an enzymatic agent while the CELL-DYN 1800 has a separate enzymatic cleaner.

The CELL-DYN Emerald aspirates K_2EDTA-anticoagulated human whole blood specimens while the CELL-DYN 1800 uses K_3EDTA-anticoagulated human whole blood specimens.

The CELL-DYN Emerald sample size is approximately 9.8 micro liters while the CELL-DYN 1800 is approximately 30 micro liters.

Similarities and Differences Table:

	Predicate Device **Abbott CELL-DYN® 1800**	**Submission Device** **CELL-DYN Emerald™**
Device Description	Bench top analyzer with built-in monitor and data station	Same
Instrument Size	Height: 17 inches (44 cm) Width: 26 inches (66 cm) Depth: 21 inches (53 cm)	Height: 13.8 inches (35 cm) Width: 9.8 inches (25 cm) Depth: 13.8 inches (35 cm)
Intended Use	The CELL-DYN 1800 is a multi-parameter, automated hematology analyzer designed for in vitro diagnostic use in clinical laboratories.	The CELL-DYN Emerald is an automated hematology analyzer designed for in vitro diagnostic use in clinical laboratories.

	Predicate Device Abbott CELL-DYN® 1800	Submission Device CELL-DYN Emerald™
WBC Differential	3-Part Differential	Same
Parameters	**White Blood Cells:**	• Same
	• WBC • GRAN • LYM • %GRAN • %LYM • MID • %MID	
	Red Blood Cells: • RBC • MCV • HCT • RDW	
	Hemoglobin: • HGB • MCH • MCHC	
	Platelets: ▪ PLT ▪ MPV	
Technology	• Electrical impedance	• Same
	• LED Hemoglobin Analysis	• Same
	• Lysate modified differential	• Same
	• Modified Methemoglobin for hemoglobin measurement	• Same
	• Boards: Single Board Computed	• Boards: Pre-Amp, CPU, IHM
	• Microprocessor: Celeron 850 MHz	• Microprocessor: Freescale Coldfire
	• No Password Protection	• Password Protection
Time to First Result	Approximately 60 seconds	Same
Sampling / Dilution	**Open Mode Analysis:** Manual presentation and aspiration of a well-mixed whole blood specimen for automated	**Open Mode Analysis:** Manual presentation and aspiration of a well-mixed whole blood specimen for automated

	Predicate Device Abbott CELL-DYN® 1800	Submission Device CELL-DYN Emerald™
	analysis; automatic dilution of the aspirated sample and automatic presentation of each dilution for measurement. **Pre-Dilute Mode Analysis:** Off line dilution of whole blood specimen and manual presentation of each dilution for measurement; manual presentation and aspiration of pre-diluted sample for automated analysis.	analysis; automatic dilution of the aspirated sample and automatic presentation of each dilution for measurement.
Specimen Type	K_3EDTA-anticoagulated human whole blood for all parameters	K_2EDTA-anticoagulated human whole blood for all parameters
Sample Size	**Open Mode Analysis:** • 30 µL **Pre-Dilute Mode Analysis:** • 40 µL	**Open Mode Analysis:** • 9.8µL
Reagents	• Detergent • Diluent • CN-Free Lyse Reagent	• Cleaner (with enzymes) • Diluent • CN-Free Lyse Reagent
Histograms	RBC, WBC, PLT	Same
Data Output / Data Input Interface	**Data Output:** • Host RS232 • Color Monitor • Dot Matrix Printer • Inkjet Printer • Diskettes **Data Input:** • Keyboard (external) • Bar code reader (optional)	**Data Output:** • Host RS232 • Ethernet • Color Monitor • Dot Matrix Printer • Inkjet Printer • USB Printer **Data Input:** • Keypad (internal) • Bar code reader (standard)
Alphanumeric Specimen ID	Yes	Same

	Predicate Device Abbott CELL-DYN® 1800	Submission Device CELL-DYN Emerald™
Electrical, Mechanical, and Thermal Safety	System certification to US and Canadian product safety standards and EU low voltage safety standards	Same

Equivalency Data Summary

The CELL-DYN Emerald System is an automated hematology analyzer for *in vitro* diagnostic use in clinical laboratories. The CELL-DYN Emerald System, which includes reagents and software, was compared in both external as well as an internal clinical trial to the CELL-DYN 1800 System. The data compiled supports the claim that the CELL-DYN Emerald System is substantially equivalent to the CELL-DYN 1800 System and includes data for background, correlation, precision, linearity and carryover. Refer to Medical Clinical Summary Report (Attachment F) for the data supporting the substantially equivalent claim between the CELL-DYN Emerald and the CELL-DYN® 1800.

Conclusion

The CELL-DYN Emerald System is substantially equivalent to the CELL-DYN® 1800 (predicate device). The differences noted do not pose new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Abbott Laboratories
c/o Ms Michelle B. Roeding
Section Manager, Regulatory Affairs
5440 Patrick Henry Drive
Santa Clara, CA 95054

Re: k081495
Trade/Device Name: Cee-Dyn Emerald™ System
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: January 16, 2009
Received: January 21, 2009

Dear Ms. Roeding:

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,

Maria M. Chan

Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K081495

Device Name: CELL-DYN Emerald™ System

Indication For Use:

The CELL-DYN Emerald is an automated hematology analyzer designed for in-vitro diagnostic use in clinical laboratories.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K081495