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510(k) Summary

CELL-DYN Emerald 22 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: K110381

Submitted by	**Contact Person**
Abbott Laboratories	Michelle Roeding
5440 Patrick Henry Drive	Global Regulatory Affairs Section Manager
Santa Clara, CA 95054	Phone: (408) 567-3781
	Fax: (408) 588-2927

Date Prepared: August 2, 2011

Proprietary Name: CELL-DYN Emerald 22 System

Common Name: Automated Hematology Analyzer

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

Predicate Device: Abbott CELL-DYN 3700 System, K991605

Device Description:

The CELL-DYN Emerald 22 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 22 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 22 System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro-diagnostic use in clinical laboratories for enumeration of the following parameters: WBC, LYM%, LYM # , MON%, MON # , NEU%, NEU #, EOS% , EOS # , BAS%, BAS #, RBC, HCT, MCV, RDW, HGB, MCH, MCHC, PLT, MPV in K_2EDTA anti-coagulated whole blood.

The CELL-DYN Emerald 22 is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.

Similarities and Differences

The CELL-DYN Emerald 22 System and the CELL-DYN 3700 System are similar in that:

a) Both systems aspirate the specimen from a collection tube, which contains the EDTA-anticoagulated human whole blood specimen, and present it for automated processing.

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

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

d) Both systems provide dispersional data alerts, suspect parameter messages, and critical limit flagging.

e) Both systems use LED hemoglobin analysis.

f) Both systems use a cyanide-free differential lyse reagent.

g) Both systems are capable of inputting specimen information from a bar code through a hand held bar code scanner.

h) Both systems are capable of data output to a printer.

i) Both systems use optical analysis for the five-part white blood cell differential.

The CELL-DYN Emerald 22 System and the CELL-DYN 3700 System are different in that:

a) The CELL-DYN Emerald 22 is smaller and more compact than the CELL-DYN 3700.

b) The CELL-DYN Emerald 22 is open mode and the CELL-DYN 3700 is open, or closed mode, and has the option of a sample loader.

c) The CELL-DYN Emerald 22 has patient storage capacity of 1,000 records, while the CELL-DYN 3700 has a patient storage capacity of 10,000 run cycles.

d) The CELL-DYN Emerald 22 has a touch screen and built in keypad, while the CELL-DYN 3700 has an external keyboard and monitor.

e) The CELL-DYN Emerald 22 has two USB ports, two serial ports and an internet port, while the CELL-DYN 3700 has a floppy drive and serial port for printing and data storage options.

f) The CELL-DYN Emerald 22 has password protection to secure software fields, while the CELL-DYN 3700 does not have password protection.

g) The CELL-DYN Emerald 22 has a lock out feature to ensure expired reagents cannot be used on the system, while the CELL-DYN 3700 has no reagent lock out feature.

h) The CELL-DYN Emerald 22 has 6 control files, while the CELL-DYN 3700 has 20 control files.

i) The CELL-DYN Emerald 22 sample volume is 28 micro liters while the CELL-DYN 3700 nominal aspiration volume is 130 micro liters in open mode, and 240 micro liters in the closed mode.

j) The CELL-DYN Emerald 22 uses a light emitting diode (LED) for optical analysis of the five-part white blood cell differential, while the CELL-DYN 3700 uses a He-Ne laser.

k) The CELL-DYN Emerald 22 does not measure reticulocytes, while the CELL-DYN 3700 does measure reticulocyte parameters.

Similarities and Differences Table:

	Predicate Device CELL-DYN 3700	**Submission Device CELL-DYN Emerald 22**
Device Description	Bench top analyzer with built in loader	Bench top analyzer
Instrument Size Closed Sample Model	Height: 24 inches (61 cm) Width: 30 inches (76 cm) Depth: 22 inches (56 cm)	Height: 13.8 inches (35 cm) Width: 9.8 inches (25 cm) Depth: 13.8 inches (35 cm)
Instrument Size Sample Loader Model	Height: 27 inches (68 cm) Width: 30 inches (76 cm) Depth: 31 inches (79 cm)	Not applicable
Intended Use	The CELL-DYN 3700 is a multi-parameter, automated hematology analyzer designed for in vitro diagnostic use in clinical laboratories.	The CELL-DYN Emerald 22 System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro-diagnostic use in clinical laboratories for enumeration of the following parameters: WBC, LYM%, LYM # , MON%, MON # , NEU%, NEU #, EOS% , EOS # , BAS%, BAS #, RBC, HCT, MCV, RDW, HGB, MCH, MCHC, PLT, MPV in K_2EDTA anti-coagulated whole blood. The CELL-DYN Emerald 22 is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.
WBC differential	5-part differential	Same

	Predicate Device CELL-DYN 3700	Submission Device CELL-DYN Emerald 22
Parameters	White Blood Cells: WBC LYM LYM% MONO MONO% NEU NEU% EOS EOS% BASO BASO%	Same
	Red Blood Cells: RBC HCT MCV RDW	Same
	Hemoglobin: HGB MCH MCHC	Same
	Platelets: PLT MPV	Same
	Reticulocyte: RETIC RETIC % IRF	Not applicable
Technology	• Electrical impedance • LED Hemoglobin Analysis at 555 nm • Optical differential • 5mW HeNe Laser	• Same • Same • Same • 455 nm light emitting diode
Throughput	Approximately 90 per hour	Approximately 45 per hour
Sampling	Open or Closed Mode Analysis Manual or loader presentation	Open Mode Analysis Manual presentation and

	Predicate Device CELL-DYN 3700	Submission Device CELL-DYN Emerald 22
	and aspiration of a well-mixed whole blood specimen for automated analysis; automatic dilution of the aspirated sample and automatic presentation of each dilution for measurement.	aspiration of a well-mixed whole blood specimen for automated 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 130 µL Closed Mode Analysis 240 µL	Open Mode Analysis 28 µL
Reagents	Diluent CN-Free Lyse Reagent Enzymatic Cleaner Detergent Sheath Reagent Reticulocyte Reagent	Diluent CN-Free Lyse Reagent CELL-DYN Easy Cleaner
	No reagent lock out feature	Reagents lock out feature to ensure expired reagents cannot be used on the system
Histograms	WBC, PLT, RBC	Same
Data Output/Input	Data Output: Host RS232 Color Monitor external Printer Floppy drive Data Input: Keyboard Bar code reader (optional)	Data Output: Host RS232, Ethernet Color LCD internal Printer USB Data Input: On screen Keypad Bar code reader (standard)
Patient Data Storage	10,000 cycles	1,000 records
Alphanumeric Specimen ID	Yes	Same
Quality Control	20 files	6 files

	Predicate Device CELL-DYN 3700	Submission Device CELL-DYN Emerald 22
Controls	CELL-DYN 26 Plus Control and CELL-DYN HemCal Plus Calibrator	CELL-DYN 22 Plus Control and CELL-DYN 22 Plus Calibrator

Equivalency Data Summary

The CELL-DYN Emerald 22 System is an automated hematology analyzer for *in vitro* diagnostic use in clinical laboratories. The CELL-DYN Emerald 22 System, which includes reagents and software, was compared to the CELL-DYN 3700 System in a clinical trial. The data compiled supports the claim that the CELL-DYN Emerald 22 System is substantially equivalent to the CELL-DYN 3700 System. The system evaluation included data for background, correlation, precision, linearity and carryover.

Conclusion

The CELL-DYN Emerald 22 System is substantially equivalent to the CELL-DYN 3700 (predicate device). The differences noted between the systems do not pose new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Abbott Laboratories
Diagnostics Division
c/o Ms. Michelle B. Roeding
Section Manager, Regulatory Affairs
5440 Patrick Henry Drive
Santa Clara, CA 95054

DEC 2 2 2011

Re: k110381
Trade/Device Name: CELL-DYN Emerald 22 System
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: December 21, 2011
Received: December 22, 2011

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 Parts 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,

Maria M. Chan

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

Enclosure

Indications for Use Form

510(k) Number (if known): K110381

Device Name: CELL-DYN Emerald 22

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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 In Vitro Diagnostic Devices (OIVD)

Maria M Chan

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

510(k) K110381