JUN 23 1999

K991142

II. 510(k) Summary per 21 CFR807.92

Submitted By:	Abbott Laboratories 5440 Patrick Henry Drive Santa Clara, CA 95054
Contact Person:	Janice E. Brown (408) 567-3521
Date Prepared:	April 2, 1999
Proprietary Name:	CELL-DYN® 1200 System
Common Name:	Automated Hematology Analyzer
Classification Name:	Automated Differential Cell Counter 21 CFR 864.5220
Predicate Devices:	CELL-DYN® 1700 System, K870233 Manual Differential

Description of Device:

The CELL-DYN® 1200 System is a single unit device with a stand alone printer used in the clinical laboratory setting. The Analyzer aspirates, dilutes, mixes and analyzes each whole blood specimen. The computer in the Analyzer controls all system processing, provides the primary operator interface with the system, and controls the optional printer, which generates reports.

The CELL-DYN® 1200 System is a multi-parameter, automated hematology analyzer designed to use EDTA-anticoagulated whole blood specimens to count, size and classify cells by using an focused flow impedance transducer, equipped with two non-corrosive electrodes to measure WBCs, RBCs, and PLTs. The HGB is measured colorimetrically in the HGB transducer by an LED light source and a light sensitive diode. The analyzer is menu-driven and controlled by a microprocessor.

II. 510(k) Summary per 21 CFR807.92 (cont.):

Intended Use:

The CELL-DYN® 1200 System is a multi-parameter hematology analyzer intended to classify the following formed elements of EDTA anti-coagulated blood:

White Blood Cell Parameters: WBC – White Blood Cell or leukocyte count GRAN –Granulocyte absolute count %GRAN -- Granulocyte percent LYM – Lymphocyte absolute count %L – Lymphocyte percent MID – Mid-range absolute count %M – Mid-range percent Platelet Parameters: PLT – Platelet Count MPV – Mean Platelet Volume *PDW – Platelet Distribution Width *PCT – Plateletcrit * Clinical significance has not been established for these parameters. Therefore, they are not reportable in the US.	Red Blood Cell Parameters: RBC -- Red Blood Cell or erythrocyte count HCT – Hematocrit MCV -- Mean Corpuscular Volume RDW -- Red Cell Distribution Width Hemoglobin Parameters: HGB – Hemoglobin Concentration MCH -- Mean Cell Hemoglobin MCHC – Mean Cell Hemoglobin Concentration

Technological Characteristics:

The CELL-DYN® 1200 System utilizes the following technologies: optical absorbance methods; focused flow impedance; microprocessors for systems control, data acquisition, and data analysis; video keypads, liquid crystal display (LCD), optional printer and an on-line LIS interface.

Similarities and Differences:

The following table describes the various parameters, subsystems and interfering substances of the CELL-DYN® 1200 System as compared to the predicate device the CELL-DYN® 1700 System.

The two systems are similar in that:

a) Both systems provide quantitation of the hemogram parameters in EDTA-anticoagulated human whole blood specimens.
b) Both systems will accept specimens presented manually by the operator.
c) Both systems automatically aspirate the specimen and present it for automated processing.

II. 510(k) Summary per 21 CFR807.92 (cont.):

Similarities and Differences (cont'd):

The two systems are similar in that:

d) Both systems utilize optical absorbance methods.
e) Both systems use microprocessors for systems control, data acquisition, and data analysis.
f) Both systems accept input from keypads and output data to a video screen, diskette, optional printer, and on-line LIS.
g) Both systems provide distributional flags to assist in data review.

The two systems are different in that:

a) The CELL-DYN® 1200 System utilizes a focused flow impedance measurement, while the CELL-DYN® 1700 System utilizes impedance.
b) The CELL-DYN® 1700 utilizes both a keyboard and a hard drive for data operations, while the CELL-DYN® 1200 utilizes keypads and a diskette.
c) The CELL-DYN® 1200 uses a cyanide free hemoglobin reagent while the CELL-DYN® 1700 utilizes a cyanide containing hemoglobin reagent.
d) The CELL-DYN® 1200 utilizes a liquid crystal monochrome display while the CELL-DYN® 1700 utilizes high resolution color monitor.

II. 510(k) Summary per 21 CFR807.92 cont.:

Table: Comparison of the CELL-DYN® 1200 to the CELL-DYN® 1700

	CELL-DYN® 1200	*CELL-DYN® 1700 K870233*
Intended Use	The CELL-DYN® 1200 System is a multi-parameter, automated hematology analyzer intended to classify the following formed elements of EDTA anti-coagulated blood:	Same
Measurement(s) and (Parameters)	**Focused Flow Impedance** • White Blood Cell (WBC) Count • Lymphocyte # and % • Mid Cells # and % • Granulocyte # and % • Red Blood Cell (RBC) Count • Red Cell Distribution Width (RDW) • Mean Corpuscular Volume (MCV) • Platelet (PLT) Count • Mean Platelet Volume (MPV) • Plateletcrit (PCT)** • Platelet Distribution Width (PDW)** *** for laboratory use only; not reportable in US*	**Impedance** • White Blood Cell (WBC) Count • Lymphocyte # and % • Mid Cells # and % • Granulocyte # and % • Red Blood Cell (RBC) Count • Red Cell Distribution Width (RDW) • Mean Corpuscular Volume (MCV) • Platelet (PLT) Count • Mean Platelet Volume (MPV) • Plateletcrit (PCT)** • Platelet Distribution Width (PDW)** *** for laboratory use only; not reportable in US*
	Optical Absorbance • Hemoglobin (HGB) Calculated values: • Hematocrit (HCT) • Mean Cell Hemoglobin (MCH) • Mean Cell Hemoglobin Concentration (MCHC)	**Optical Absorbance** • Hemoglobin (HGB) Using Modified Cyanmethemoglobin Calculated values: • Same
Device Description	**Main Components:** • Analyzer w/integrated display/keypad	Same
Interface **(Data Output/ Data Input)**	**Data Output:** • ¼ VGA LCD Display, High Resolution Monochrome • Printer (optional) • RS232 LIS Interface Port	• High Resolution Color Monitor
	Data Input: • Keypad	• Keypad • Keyboard
Specimen Type	EDTA (K_3, K_2) Anticoagulated Human Whole Blood	Same

II. 510(k) Summary per 21 CFR807.92 cont.:

Table: Comparison of the CELL-DYN® 1200 to the CELL-DYN® 1700

	CELL-DYN® 1200	*CELL-DYN® 1700 K870233*
Sampling	• Direct sampling of a well mixed whole blood specimen from an open or closed collection tube that has been identified and presented manually by the operator.	Same
Dilution	• Automatic dilution of the aspirated sample and presentation of each dilution for measurement.	Same
Operating Principles	• Enumeration and sizing of WBCs, RBCs, and PLTs by impedance	Same
	• HGB is measured by optical absorbance.	Same
Potential Interfering Substances	• **WBC** • NRBCs • Lyse Resistant RBCs • PLT clumps • Cryoglobulin and cryofibrinogen	Same
	RBC • Elevated WBCs • Increased # giant PLTs • Autoagglutination • *In vitro* hemolysis	Same
	HGB • Elevated WBC • Increased plasma substances (triglycerides, bilirubin, *in vivo* hemolysis) • Lyse Resistant RBCs	Same
	MCV • Elevated WBCs • Increased # giant PLTs • Hyperglycemia • *In vitro* hemolysis	Same

II. 510(k) Summary per 21 CFR807.92 cont.:

Table: Comparison of the CELL-DYN® 1200 to the CELL-DYN® 1700

	CELL-DYN® 1200	*CELL-DYN® 1700 K870233*
Potential Interfering Substances Cont.	**PLT** • WBC fragments • Increased # giant PLTs • Microcytic RBCs • PLT clumping • Cryoglobulins • *In vitro* hemolysis	Same
	• **MPV** • None Stated	Same

Equivalency Data:

The data compiled to support the claim that the CELL-DYN® 1200 System is substantially equivalent to the CELL-DYN® 1700 and the manual differential includes background, carryover, precision, correlation, linearity, and flagging data. Equivalence is demonstrated between the CELL-DYN® 1200 System and the CELL-DYN® 1700 System for the following measured parameters: White Blood Cell (WBC), three part WBC Differential sub-populations, Red Blood Count (RBC), Hemoglobin concentration (HGB), Mean Corpuscular Volume (MCV), Red Cell Distribution Width (RDW), Platelet Count (PLT), Mean Platelet Volume (MPV). Background, carryover, precision, correlation, and linearity data show performance to manufacturer's specifications.

Conclusion:

The conclusion of the testing performed on the CELL-DYN® 1200 System at Abbott Laboratories, Santa Clara, CA demonstrates the device is as safe and effective and performs as well as or better than the CELL-DYN® 1700 System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 23 1999

Ms. Janice E. Brown
Regulatory Affairs Manager
Abbott Laboratories
5440 Patrick Henry Drive
Santa Clara, California 95054

Re: K991142
Trade Name: CELL-DYN® 1200 System
Regulatory Class: II
Product Code: GKZ
Dated: April 2, 1999
Received: April 5, 1999

Dear Mr. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VI. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K991142

Device Name: CELL-DYN® 1200 System

Indications For Use:

The CELL-DYN® 1200 is a multi-parameter hematology analyzer intended to classify the following formed elements of EDTA anti-coagulated blood:

White Blood Cell Parameters:
WBC – White Blood Cell or leukocyte count
GRAN –Granulocyte absolute count
%GRAN -- Granulocyte percent
LYM – Lymphocyte absolute count
%L – Lymphocyte percent
MID – Mid-range absolute count
%M – Mid-range percent
Platelet Parameters:
PLT – Platelet Count
MPV – Mean Platelet Volume
*PDW – Platelet Distribution Width
*PCT – Plateletcrit

Red Blood Cell Parameters:
RBC -- Red Blood Cell or erythrocyte count
HCT – Hematocrit
MCV -- Mean Corpuscular Volume
RDW -- Red Cell Distribution Width

Hemoglobin Parameters:
HGB – Hemoglobin concentration
MCH -- Mean Cell Hemoglobin
MCHC – Mean Cell Hemoglobin Concentration

* Clinical significance has not been established for these parameters. Therefore, they are not reportable in the US

Peter E Maleri

(Division Sign-Off)
Division of Clinical Laboratory Devices K991142
510(k) Number

Prescription ✓