13. (cont'd)

510(k) SUMMARY
CELL-DYN® 1200 System

Intended Use

The CELL-DYN® 1200 System is an automated multi-parameter hematology analyzer intended for *in-vitro* diagnostic use in the clinical hematology laboratory, medical clinic and/or Physicians Office Laboratory (POL) 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.

Principles of Operation

The CELL-DYN 1200 System counts, sizes, and classifies blood cells by impedance and focused flow methods, which incorporates electrical resistance and electronic sizing principles. Each specimen is aspirated, diluted and mixed before the hematology parameters are measured. The CELL-DYN 1200 System utilizes a spectrophotometric method for hemoglobin concentration, which is measured optically by absorbance at 540nm ±20nm. The system incorporates the coincidence loss principle for each cell that is counted.

Similarities and Differences

The CELL-DYN 1200 System operating in the POL is the same as the CELL-DYN 1200 System operated in the Clinical Laboratory.

Equivalency Data

The data compiled to support the claim that the CELL-DYN 1200 System is substantially equivalent when used either in a POL or in a Clinical Laboratory includes background, carryover, accuracy, precision,

510(k) SUMMARY
CELL-DYN® 1200 System

Equivalency Data (cont'd)

linearity and quality control. Correlation equivalence is demonstrated between the CELL-DYN 1200 System and the CELL-DYN 1700 System for the following measured parameters: White Blood Count (WBC), WBC differential sub populations, Red Blood Count (RBC), Hemoglobin concentration (HGB), Mean Corpuscular Volume (MCV), Platelet Count (PLT), Mean Platelet Volume (MPV), and Red Cell Distribution Width (RDW).

Conclusion

The modified device has demonstrated comparable performance characteristics to the predicate device when operated in the POL environment and supports the labeling change to include placement in POLs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 24 1999

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

Re: K992444
Trade Name: CELL-DYN® 1200 System
Regulatory Class: II
Product Code: GKZ
Dated: July 21, 1999
Received: July 22, 1999

Dear Ms. 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

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

14. Indications for Use Statement

10(k) Number (if known): K992444

Device Name: **CELL-DYN® 1200 System**

Indications for Use:

The CELL-DYN 1200 System is an automated, multi-parameter hematology analyzer intended for *in-vitro* diagnostic use in the clinical hematology laboratory, medical clinic and/or Physician's Office Laboratory (POL) to classify the following formed elements of EDTA anti-coagulated blood:

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Platelet Parameters:	MCHC – Mean Cell Hemoglobin Concentration
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.	

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Mahn

(Division Sign-Off)
Division of Clinical Laboratory Devices K992444
510(k) Number

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