AUG 12 1997

510(k) SUMMARY

CELL-DYN®4000 Multi-Parameter Automated Hematology Analyzer with Immature Reticulocyte Fraction (IRF)

510(k) Summary Of Safety And Effectiveness Information Supporting A Substantially Equivalent Determination

The following information as presented in the Premarket Notification (510(k) for the Cell-Dyn® 4000 System Hematology Analyzer with IRF constitutes data supporting a substantially equivalent determination.

The methods of determination are those used by the Coulter® ZBI, Coulter, Hemoglobinometer, Coulter Model S, Coulter Model S Plus Series, Coulter STKS, Cell-Dyn®4000 System, Cell-Dyn®3500R, Technicon H*1™ Series; Becton Dickinson FACScan™™, the Sysmex™ R-3000, and the manual reticulocyte method. These methods collectively perform one or more of the determinations which are combined in the Cell-Dyn® 4000 System with IRF.

Intended Use

The Cell-Dyn 4000 System with IRF is a multi-parameter, hematology analyzer designed for In-Vitro diagnostic use in clinical laboratories.

Device Description

The Cell-Dyn® 4000 System has five main modules: the Analyzer, which aspirates, dilutes and analyzes each whole blood specimen; the Autoloader, which automatically identifies, mixes, and presents specimens for processing; the Pneumatic Unit, which controls fluid movement in the Analyzer and tube movement in the Autoloader; the Data Station, which controls all system processing and provides the primary operator interface with the system; and the Color Printer, which generates reports automatically or on demand.

The Cell-Dyn 4000 System with IRF is designed to analyze EDTA-anticoagulated whole blood specimen and report the hematological parameters shown in the table on the following page.

Cell-Dyn®4000 System with IRF Parameters:

White Blood Cell Parameters:	Red Blood Cell Parameters:
WBC -- White Blood Cell or leukocyte count	RBC -- Red Blood Cell or erythrocyte count
NEU -- Neutrophil absolute count	HCT -- Hematocrit
%N -- Neutrophil percent	MCV -- Mean Corpuscular Volume
LYM -- Lymphocyte absolute count	RDW -- Red Cell Distribution Width
%L -- Lymphocyte percent	NRBC -- Nucleated Red Blood Cell absolute count
MONO -- Monocyte absolute count	NR/W -- Nucleated Red Blood Cell percent of WBC count
%M -- Monocyte percent	Hemoglobin Parameters:
EOS -- Eosinophil absolute count	HGB -- Hemoglobin concentration
%E -- Eosinophil percent	MCH -- Mean Corpuscular Hemoglobin
BASO -- Basophil absolute count	MCHC -- Mean Corpuscular Hemoglobin Concentration
%B -- Basophil percent	
*vWF -- Viable White Cell fraction	
*BAND -- Band Neutrophil absolute count	Reticulocyte Parameters:
*%BD -- Band Neutrophil percent	RETC -- Reticulocyte concentration
*IMMG -- Immature Granulocyte absolute count	%R -- Reticulocyte percent of RBC count
	IRF -- Immature Reticulocyte Fraction
*%IG -- Immature Granulocyte percent	Platelet Parameters:
*BLST -- Blast absolute count	PLT -- Platelet Count
*%BL -- Blast percent	MPV -- Mean Platelet Volume
*VARL -- Variant Lymphocyte absolute count	*PDW -- Platelet Distribution Width
*%VL -- Variant Lymphocyte percent	*PCT -- Plateletcrit

* These parameters are provided for laboratory use only and are not reportable in the US.

Principles of Operation

The analyzer counts, sizes and classifies blood cells by the combination of flow cytometry methods: Laser Optical Scatter and Fluorescence, Focused Flow Impedance, and Absorption Spectrophotometry. The IRF is derived from the intensity of the fluorescence measured for the Reticulocyte parameters. The Cell-Dyn® 4000 System uses an Argon-ion laser as the optical light source. The Optical Bench detects light in the form of scatter from blood cell surfaces and internal structures, or fluorescent light from specially stained blood cells.

For the WBC parameters and NRBCs, whole blood is diluted with a reagent containing a red fluorescent dye. Data are simultaneously collected for four angles (0°, 7°, 90°, and 90°D) of scatter and red fluorescence (FL3) as each cell passes through the laser beam. NRBCs, identified by fluorescence, are excluded automatically from the WBC count.

For the RBC and the PLT parameters, whole blood is diluted with a reagent that prepares the cells for measurement. The dilution is split and measured by both laser optical scatter (7° and 90°) and Focused Flow Impedance with Injection Metering.

For the hemoglobin parameters, whole blood is diluted with a cyanide free reagent and the hemoglobin is measured optically by absorbance (540nm).
For the reticulocyte parameters, an aliquot of the RBC/PLT dilution is diluted with a reagent containing a green fluorescent dye. Data are collected for scatter (7°) and green fluorescence (FL1) as each cell passes through the laser beam.

Similarities and Differences

The Cell-Dyn® 4000 System, Coulter® Counters (Model ZBI, S-Plus Series and STKS), Abbott Cell-Dyn® 3000 Series, and the Cell-Dyn® 4000 System with IRF are similar in that they use impedance for counting and sizing RBCs and PLTs. The Cell-Dyn 4000 System with IRF and the Sysmex™ NE series are similar in that they both use Focused Flow Impedance to count and size RBCs and PLTs. The Technicon H*1™ series and the Cell-Dyn® 4000 System with IRF are similar in that they both use Injection Metering to measure RBCs and PLTs optically. The Cell-Dyn® 4000 System with IRF is different in that it counts RBCs and PLTs by both the optical and impedance methods and compares the data as an internal quality check.

WBCs are counted and classified by the Cell-Dyn® 4000 System, Abbott Cell-Dyn® 3000 Series Systems and the Cell-Dyn® 4000 System with IRF in a very similar manner using four simultaneously collected angles of laser light scatter. They are different in that the Abbott Cell-Dyn® 3000 Series Systems use a helium neon laser, while the Cell-Dyn® 4000 System and the Cell-Dyn®4000 System with IRF use an Argon-ion laser that allows fluorescent data to be collected simultaneously with the optical scatter data. This change enables the Cell-Dyn 4000 System and the Cell-Dyn 4000 System with IRF to count and classify WBCs, NRBCs, and fragile (nonviable) WBCs. The Becton Dickinson FACScan™, the Cell-Dyn® 4000 System, and the Cell-Dyn 4000 System with IRF all use an Argon-ion laser. The FACScan is also capable of identifying NRBCs and non-viable WBCs. NRBCs are stained for enumeration by both the Cell-Dyn® 4000 System and the manual microscopic differential.

The Becton Dickinson FACScan™, the Sysmex™ R-3000, the Cell-Dyn® 4000 System, and the Cell-Dyn® 4000 System with IRF are similar in that they enumerate reticulocytes in EDTA-anticoagulated whole blood using optical laser scatter and fluorescence. They are different in that for the Becton Dickinson FACScan™, specimens are externally stained with Thiazol Orange an incubated for 90 minutes and then manually presented for measurement. For the Sysmex™ R-3000, specimens are automatically diluted and stained using Auromine Orange and then measured. The Cell-Dyn® 4000 System and the

Cell-Dyn® 4000 System with IRF are different in that they automatically dilute the specimen with a fast acting proprietary dye which requires no incubation prior to measurement.

Equivalency Data

The data complied to support the claim that the Cell-Dyn® 4000 System with IRF is substantially equivalent to the Abbott the Cell-Dyn® 4000 and Cell-Dyn® 3500 Systems includes accuracy, precision, linearity, and carryover. The data supports the claim that the Cell-Dyn® 4000 System with IRF is substantially equivalent to the Abbott Cell-Dyn® 4000 System and Abbott Cell-Dyn® 3500 System for the hemogram and automated WBC differential parameters and to the Abbott Cell-Dyn® 4000 System, the Becton Dickinson FACScan™, and the Sysmex™ R-3000 for the reticulocyte parameters. The accuracy, precision, and linearity data shows performance to manufacturer's specifications.

Conclusion

The Cell-Dyn® 4000 System with IRF shows an evolution of the technologies used on one or more of the currently available analyzers to count, size, and classify whole blood cells and their related parameters, and more specifically to the technologies used on the Cell-Dyn® 4000 System, Abbott Cell-Dyn® 3500 System, the Becton Dickinson FACScan™ and the Sysmex™ R-3000.

The 510(k) Summary was prepared and submitted by:

Sherry Haiflich
Sr. Regulatory Affairs Specialist
Abbott Diagnostics
5440 Patrick Henry Drive
Santa Clara, CA 95054

Phone: 408 567-3385
Fax: 408 982-4863

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Sherry Haiflich
Senior Regulatory Affairs Specialist
Abbott Laboratories
Abbott Diagnostics Division
5440 Patrick Henry Drive
Santa Clara, California 95054

AUG 12 1997

Re: K971152/S1
Trade Name: Immature Reticulocyte Fraction, Cell-Dyn® 4000 System
Regulatory Class: III
Product Code: GKZ
Dated: July 3, 1997
Received: July 7, 1997

Dear Ms. Haiflich:

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 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 requirement, 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

510(k) Number(if known)_____

Device Name: Cell-Dyn 4000 System with Immature Reticulocyte Fraction

Indications for use:

The Cell-Dyn 4000 System with Immature Reticulocyte Fraction is a fully automated hematology analyzer, including reporting of the Immature Reticulocyte Fraction, intended for in vitro diagnostic use in the clinical hematology laboratory of a hospital, medical clinic, or reference laboratory.

Peter E Maxim

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)