K991605

JUL - 9 1999

16. 510(k) Summary

CELL-DYN 3500 System and the CELL-DYN 3700 System with Immature Reticulocyte Fraction (IRF)

Submitted by:	Abbott Laboratories 5440 Patrick Henry Drive Santa Clara, CA 95054
Contact Person:	Michelle B. Roeding Phone: 408 567-3781 Fax: 408 982-4863
Date Prepared:	May 7, 1999
Proprietary Name:	CELL-DYN 3500 System with Immature Reticulocyte Fraction (IRF) CELL-DYN 3700 System with Immature Reticulocyte Fraction (IRF)
Common Name:	Automated Hematology Analyzers
Classification Name:	Automated Differential Cell Counter (21 CFR 864.5220)
Predicate Device:	CELL-DYN 4000 System, 510(k) #971152/S1

16. 510(k) Summary (cont'd)

CELL-DYN 3500 System and the CELL-DYN 3700 System with Immature Reticulocyte Fraction (IRF)

Intended Use

The CELL-DYN 3500 and the CELL-DYN 3700 Systems are automated, multi-parameter hematology analyzers intended to classify the following formed elements of EDTA anti-coagulated blood including:

White Blood Cell Parameters: WBC -- White Blood Cell or Leukocyte Count NEU -- Neutrophil Absolute Count %N -- Neutrophil Percent LYM -- Lymphocyte Absolute Count %L -- Lymphocyte Percent MONO -- Monocyte Absolute Count %M -- Monocyte Percent EOS -- Eosinophil Absolute Count %E -- Eosinophil Percent BASO -- Basophil Absolute Count %B -- Basophil Percent	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 Corpuscular Hemoglobin MCHC -- Mean Corpuscular Hemoglobin Concentration
Platelet Parameters: PLT -- Platelet Count MPV -- Mean Platelet Volume *PDW -- Platelet Distribution Width *PCT -- Plateletcrit	Reticulocyte Parameters: RETC -- Reticulocyte Concentration %R -- Reticulocyte Percent of RBC Count **IRF -- Immature Reticulocyte Fraction**

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

Device Description:

The CELL-DYN 3500 and the CELL-DYN 3700 Systems have four main modules: 1) the Analyzer, which aspirates, dilutes and analyzes each whole blood specimen 2) the Sample Loader, which automatically identifies, mixes, and presents specimens for processing 3) the Data Station, which controls all system processing and provides the primary operator interface with the system and; 4) the Color Printer, which generates reports automatically or on demand.

16. 510(k) Summary (cont'd)

CELL-DYN 3500 System and the CELL-DYN 3700 System with Immature Reticulocyte Fraction (IRF)

Device Description (cont'd):

The analyzer counts, sizes and classifies blood cells by the combination of methods: Laser Optical Light Scatter, Impedance, and Absorption Spectrophotometry. The IRF is derived from the data measured for the Reticulocyte parameters. The CELL-DYN 3500 and the CELL-DYN 3700 Systems use a Helium-Neon laser as the optical light source. The Optical Bench detects light in the form of scatter from blood cell surfaces and internal structures.

For the reticulocyte parameters, an off-line dilution of blood and Reticulocyte Reagent is prepared and stained for 15 minutes. The dilution is aspirated and the reticulocytes are counted in the WOC channel. Data are collected for scatter (0°, 10°, and 90°) as each cell passes through the laser beam.

The CELL-DYN 3500 and the CELL-DYN 3700 Systems report Reticulocyte % and Absolute Count. The IRF is a fraction of the total reticulocyte absolute count. The CELL-DYN 3500 and the CELL-DYN 3700 Systems are designed to analyze EDTA-anticoagulated whole blood specimens and report the additional Immature Reticulocyte Parameter.

Similarities and Differences:

The CELL-DYN 3500 and the CELL-DYN 3700 Systems with IRF, and the CELL-DYN 4000 System are similar in that the systems use impedance for counting and sizing RBCs. The Reticulocyte Reagent enables both the CELL-DYN 3500 and the CELL-DYN 3700 Systems with IRF and the CELL-DYN 4000 System to count and classify mature and immature reticulocytes. The CELL-DYN 3500 and the CELL-DYN 3700 Systems with IRF and the CELL-DYN 4000 System with IRF, enumerate reticulocytes in EDTA-anticoagulated whole blood using optical laser scatter. They are different in that CELL-DYN 3500 and the CELL-DYN 3700 Systems with IRF specimens are externally stained in an off-line preparation step with New Methylene Blue while the CELL-DYN 4000 System with IRF automatically dilutes the specimen with a fast acting proprietary dye that requires no incubation prior to measurement.

16. 510(k) Summary (cont'd)

CELL-DYN 3500 System and the CELL-DYN 3700 System with Immature Reticulocyte Fraction (IRF)

Equivalency Data:

The data compiled to support the claim that the CELL-DYN 3500 and the CELL-DYN 3700 Systems IRF are substantially equivalent to the Abbott CELL-DYN 4000 System include background, accuracy, precision, linearity, and carryover. The data supports the claim that the CELL-DYN 3500 and the CELL-DYN 3700 Systems IRF parameters are substantially equivalent to the Abbott CELL-DYN 4000 System IRF parameter. The accuracy, precision, and linearity data shows performance to manufacturer's specifications. Data was collected at Scottsdale Health Care – Shea, Scottsdale, AZ; VAMC, Phoenix, AZ; and an internal Abbott Diagnostics Division site.

Conclusion:

The CELL-DYN 3500 and the CELL-DYN 3700 Systems IRF demonstrate substantial equivalence to the predicate device.

17. Financial Disclosure

Data was collected from two field clinical sites and one internal site.

The two clinical sites were Scottsdale Health Care – Shea, Scottsdale, Arizona and Veteran's Affairs Medical Center (VAMC), Phoenix, Arizona. Scottsdale Health Care was paid $14,000 on 12/11/98, VAMC was paid $5,984.78 on 12/9/98. Neither site's reimbursement exceeded $25,000.00 for this clinical study.

The internal Abbott Diagnostics Division site in Santa Clara, CA also collected data for this clinical study. Financial disclosure is not applicable as there was no payment involved.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 9 1999

Ms. Michelle B. Roeding
Regulatory Affairs Supervisor
Abbott Laboratories
Diagnostic Division
5440 Patrick Henry Drive
Santa Clara, California 95054

Re: K991605
Trade Name: CELL-DYN 3500 System with Immature Reticulocyte Fraction
CELL-DYN 3700 System with Immature Reticulocyte Fraction
Regulatory Class: III
Product Code: GKZ
Dated: May 7, 1999
Received: May 10, 1999

Dear Ms. Roeding:

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

19. Indications For Use Statement

510(k): ~~K980614/A1~~
Device Name: **CELL-DYN 3500 System with Immature Reticulocyte Fraction**
CELL-DYN 3700 System with Immature Reticulocyte Fraction

Indications for Use: The CELL-DYN 3500 and the CELL-DYN 3700 Systems are automated, multi-parameter hematology analyzers intended to classify the following formed elements of EDTA anti-coagulated blood:

WBC -- White Blood Cell or Leukocyte Count
NEU -- Neutrophil Absolute Count
%N -- Neutrophil Percent
LYM -- Lymphocyte Absolute Count
%L -- Lymphocyte Percent
MONO -- Monocyte Absolute Count
%M -- Monocyte Percent
EOS -- Eosinophil Absolute Count
%E -- Eosinophil Percent
BASO -- Basophil Absolute Count
%B -- Basophil Percent
PLT -- Platelet Count
MPV -- Mean Platelet Volume
RBC -- Red Blood Cell or Erythrocyte Count
HCT – Hematocrit
MCV -- Mean Corpuscular Volume
RDW -- Red Cell Distribution Width
HGB -- Hemoglobin Concentration
MCH -- Mean Corpuscular Hemoglobin
MCHC -- Mean Corpuscular Hemoglobin Concentration
RETC -- Reticulocyte Concentration
% RETC -- Reticulocyte Concentration
IRF -- Immature Reticulocyte Fraction
*PDW -- Platelet Distribution Width
*PCT -- Plateletcrit

* These parameters are provided for laboratory use only and 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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991605

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