510(k) SUMMARY
CELL-DYN® 3000 Series Hematology Systems
POL Supplement

510(k) Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

The following information as presented in the 510(k) Supplement to Expand the Intended Use for Physician's Office Laboratories (POLs) for the Abbott CELL-DYN®3200 (K972354), the CELL-DYN® 3500R (K960427) and the CELL-DYN® 3000 (K955673) Systems constitutes data supporting a substantially equivalent determination. These three systems are referred to as the CELL-DYN® 3000 Series. The methods of determination while operated in POLs are those used by the CELL-DYN® 3000 Series.

Intended Use

The CELL-DYN® 3000 Series are automated, multi-parameter hematology analyzers intended for *in-vitro* diagnostic use in the Clinical Laboratory and the Physician's Office Laboratory (POL).

Device Description

The CELL-DYN® 3000 Series instruments each consist of three major modules: the Analyzer, which aspirates, dilutes and analyzes each whole blood specimen; the Data Station/Module, which controls all system processing and provides the primary operator interface with the system; and the Printer, which generates reports automatically or on demand.

The CELL-DYN® 3000 Series instruments are designed to analyze K_3EDTA anticoagulated human whole blood specimens and report the hematological parameters shown in the table on the following page:

Reported 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	RETC -- Reticulocytes (CELL-DYN 3500R only)
MONO -- Monocyte absolute count	MCH -- Mean Corpuscular Hemoglobin
%M -- Monocyte percent	MCHC -- Mean Corpuscular Hemoglobin Concentration
EOS -- Eosinophil absolute count	
%E -- Eosinophil percent	Platelet Parameters:
BASO -- Basophil absolute count	
%B -- Basophil percent	PLT -- Platelet Count
	MPV -- Mean Platelet Volume
Hemoglobin Parameters:	*PDW -- Platelet Distribution Width
HGB -- Hemoglobin concentration	*PCT -- Plateletcrit

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

Principles of Operation:

The Cell-Dyn® 3000 series count, size and classify blood cells by a combination of methods: flow cytometry laser optical scatter and/or impedance. The instruments 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 WBC parameters, whole blood is diluted with a reagent to preserve cell integrity. Data are simultaneously collected for four angles (0°, 10°, 90°, and 90°D) of light scatter as each cell passes through the laser beam. For the RBC and PLT parameters, whole blood is diluted with a reagent that prepares the cells for measurement. The dilution is split and measured by laser optical scatter at (0° and 10°) or impedance.

For the hemoglobin parameter, whole blood is diluted with a cyanide free and/or cyanide containing reagent and the hemoglobin is measured optically by absorbance at 540nm.

Similarities and Differences:

The CELL-DYN® 3000 Series instruments are all similar in that they utilize Optical Laser Light Scatter from a Helium neon Laser to count and differentiate WBCs, they use anticoagulated human whole blood specimens, they automatically dilute and aspirate specimens, and specimens may be run using automated specimen processing. All count fragile WBCs, all have extended counts for WBCs and PLTs, all measure Hemoglobin by Optical Absorbance and all have internal Quality Control programs.

The CELL-DYN® 3000 Series are different in that the CELL-DYN® 3500R and the CELL-DYN® 3000 utilize impedance for counting and sizing RBCs and PLTs, while the CELL-DYN® 3200 utilizes Optical Light Scatter. Only the CELL-DYN® 3500R has the capability of counting and reporting Reticulocyte results.

Equivalency Data:

The data compiled to support the claim that the CELL-DYN® 3200 System is substantially equivalent when used in a POL to the other CELL-DYN® 3000 series instruments includes background, accuracy, precision, linearity, and carryover. Equivalence is demonstrated between the CELL-DYN® 3200 System and the CELL-DYN® 3500R 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), Red Cell Distribution Width (RDW), Platelet Count (PLT) and Mean Platelet Volume (MPV). Accuracy, precision, and linearity data show performance to manufacturer's specifications.

Conclusion:

There are more similarities between the CELL-DYN® 3000 Series of instruments than there are differences. Demonstration of the equivalence of the CELL-DYN® 3200 data to the CELL-DYN® 3500R and the similarities of the CELL-DYN® 3000 Series, provides the validation for an extension of the Intended Use to include Physician's Office Laboratories (POLs).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 24 1998

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

Re: K980614
Trade Name: Abbott Laboratories CELL-DYN® 3000 Series Hematology Systems
Regulatory Class: II
Product Code: GKZ
Dated: January 30, 1998
Received: February 2, 1998

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 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): **CELL-DYN® 3200 System (K972354)**
CELL-DYN® 3500R (K960427)
CELL-DYN® 3000 (K955673).

Device Name: **CELL-DYN® 3000 Series of Instruments**

Intended Use:

The Cell-Dyn® 3000 Series instruments are automated hematology analyzers intended for *in-vitro* diagnostic use in the clinical laboratory and the Physician's Office Laboratory (POL).

Indications For Use:

The Cell-Dyn® 3000 Series instruments process human whole blood specimens to provide a hemogram with automated differential..

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980614

Prescription Use ✓