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® 3200 System Hematology Analyzer constitutes data supporting a substantially-equivalent determination.

Substantial equivalence is demonstrated between the CELL-DYN® 3200 System and the Abbott the CELL-DYN® 3500R Multi-Parameter Automated Hematology Analyzer, #K955715 System for the White Blood Cell (WBC), Red Blood Cell (RBC), Hemoglobin concentration (HGB), Platelet count (PLT), WBC differential parameters and the calculated parameter of Mean Corpuscular Hemoglobin (MCH). Substantial equivalence is also demonstrated between the CELL-DYN® 3200 System and the CELL-DYN® 4000 System for Mean Corpuscular Volume (MCV), Red Cell Distribution Width (RDW), and Mean Platelet Volume (MPV). Substantial equivalence is demonstrated between the CELL-DYN® 3200 System and the Technicon H*3 RTC #K930148 for the hemogram and white cell (WBC) differential parameters. Additional data was collected to demonstrate the comparison of the Mean Corpuscular Volume (MCV) of the CELL-DYN® 3200 System to the manual microhematocrit method, NCCLS H7-A2. The NCCLS H20-A, "Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrumental Methods," Approved Voluntary Standard 1992 for the white cell differential parameters was used to arbitrate differences in the differential.

Intended Use:

The CELL-DYN ® 3200 System is a fully automated hematology analyzer intended for *in-vitro* diagnostic use in the clinical laboratory.

Device Description:

The CELL-DYN® 3200 System has three main modules: the Analyzer, which identifies, mixes, and presents specimens for processing, aspirates, dilutes and analyzes each whole blood specimen. The Data Module, which controls all system processing; and the Display Station , which provides the primary operator interface with the system and generates reports automatically or on demand.

The CELL-DYN® 3200 is designed to analyze K_3EDTA-anticoagulated whole blood specimens and report the following hematological parameters:

White Blood Cell Parameters:	Red Blood Cell Parameters:
WBC -- White Blood Cell	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	
MONO -- Monocyte absolute count	Hemoglobin Parameters:
%M -- Monocyte percent	HGB -- Hemoglobin concentration
EOS -- Eosinophil absolute count	MCH -- Mean Corpuscular Hemoglobin
%E -- Eosinophil percent	MCHC -- Mean Corpuscular Hemoglobin Concentration
BASO -- Basophil absolute count	
%B -- Basophil percent	Platelet Parameters:
	PLT -- Platelet Count
	MPV -- Mean Platelet Volume
	*PDW -- Platelet Distribution Width
	*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 a flow cytometry method, laser optical scatter, and colorimetric method. The CELL-DYN® 3200 System uses 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 the 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°).

For the hemoglobin parameters, whole blood is diluted with a cyanide free reagent and the hemoglobin is measured optically by absorbance (540nm).

Similarities and Differences:

The CELL-DYN® 3200 System has similarities to one or more of the methods of determination for hemogram and automated WBCs differential parameters used by the following hematology analyzers:

Abbott CELL-DYN® 3000 Series, Sysmex™ NE Series, Technicon H*1™ Series, and Abbott CELL-DYN® 4000. The CELL-DYN® 3200 is similar to the Abbott CELL-DYN® 3000 Series, Sysmex™ NE Series; Technicon H*1™ Series; and Abbott CELL-DYN® 4000 in that they use optical scatter to count and differentiate WBCs. WBCs are counted and classified by the Abbott CELL-DYN® 3000 Series Systems and the CELL-DYN® 4000 System in a very similar manner using four simultaneously collected angles of scattered laser light.

The CELL-DYN® 3200 is different from the Coulter® Counters (Model ZBI, S-Plus Series and STKS), and the CELL-DYN® 4000 System in that they use impedance for counting and sizing RBCs and PLTs. The CELL-DYN® 3200 and the Sysmex™ NE series are different in that the Sysmex uses Focused Flow Impedance to count and size RBCs and PLTs. The CELL-DYN® 3200 is different from the Technicon H*1™ series and the CELL-DYN® 4000 System in that they both use Injection Metering to measure RBCs and PLTs optically. The CELL-DYN® 4000 System 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. They are different in that the Abbott CELL-DYN® 3000 Series Systems use a helium neon laser, while the CELL-DYN® 4000 System uses an Argon-ion laser to collect optical scatter data.

Equivalency Data:

The data complied to support the claim that the CELL-DYN® 3200 System is substantially equivalent to the Abbott CELL-DYN® 3500R System includes background, accuracy, precision, linearity, comprehensive flagging and carryover. Substantial equivalence is demonstrated between the CELL-DYN® 3200 System and the Abbott the CELL-DYN® 3500R System Multi-Parameter Automated Hematology Analyzer, #K955715 for the White Blood Cell (WBC), Red Blood Cell (RBC), Hemoglobin concentration (HGB), Platelet count (PLT), WBC differential parameters and the calculated parameter of Mean Corpuscular Hemoglobin (MCH). Substantial equivalence is also demonstrated between the CELL-DYN® 3200 System and the CELL-DYN® 4000 System for Mean Corpuscular Volume (MCV), Red Cell Distribution Width (RDW), and Mean Platelet Volume (MPV). Substantial equivalence is demonstrated between the CELL-DYN® 3200 System and the Technicon H*3™ RTX #K930148 for the hemogram and white cell (WBC) differential parameters.

The data supports the claim that the CELL-DYN® 3200 System is substantially equivalent to the Abbott CELL-DYN® 3500R System for the White Blood Cell (WBC) count, Red Blood Cell (RBC) count, Hemoglobin concentration (HGB), Platelet (PLT) count, WBC differential parameters and the calculated parameter of Mean Corpuscular Hemoglobin (MCH). The data supports the claim that the CELL-DYN® 3200 System is substantially equivalent to CELL-DYN® 4000 System for MCV, RDW and MPV. The accuracy, precision, and linearity data shows performance to manufacturer's specifications. Substantial equivalence is demonstrated between the CELL-DYN® 3200 System and the Technicon H*3 RTC #K930148 for the hemogram and WBC differential parameters. The accuracy, precision, and linearity data shows performance to manufacturer's specifications.

Conclusion:

The CELL-DYN® 3200 System 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 Abbott CELL-DYN® 3500R System and the CELL-DYN® 4000 System.

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

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SEP 16 1997

Re: K972354
Trade Name: Abbott CELL-DYN 3200 System
Regulatory Class: II
Product Code: GKZ
Dated: June 20, 1997
Received: June 24, 1997

Dear Ms. Luptovic:

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): K972354

Device Name:_____

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Indications For Use:

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The CELL-DYN® 3200 System is a fully automated hematology analyzer intended for in-vitro diagnostic use in the clinical laboratory.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maher

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

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