

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

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The following information presented in the Premarket Notification 510(k) for the CELL-DYN® 4000 System constitutes data supporting a substantially-equivalent determination. Substantial equivalence is demonstrated between the CELL-DYN® 4000 System and the Abbott CELL-DYN 3500 Multi-Parameter Automated Hematology Analyzer, #K951496/S001 for the hemagram and white cell (WBC) differential parameters. Substantial equivalence is also demonstrated between the CELL-DYN® 4000 System and the Becton Dickinson FACScan™ Flow Cytometer ReticCOUNT™ Reticulocyte Enumeration Software, #K872166/A for reticulocytes. For enumeration of nucleated red blood cells (NRBCs) equivalence is demonstrated by comparison to the manual microscopic WBC differential count.

Intended Use: The CELL-DYN® 4000 System is a fully automated hematology analyzer intended for *in-vitro* diagnostic use in the clinical hematology laboratory of a hospital, medical clinic, or reference laboratory.

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 is designed to analyze EDTA-anticoagulated whole blood specimen and report the following hematological parameters:

<p>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 *vWF -- Viable White Cell fraction</p>	<p>Red Blood Cell Parameters: RBC -- Red Blood Cell or erythrocyte count HCT -- Hematocrit MCV -- Mean Corpuscular Volume RDW -- Red Cell Distribution Width NRBC -- Nucleated Red Blood Cell absolute count NR/W -- Nucleated Red Blood Cell percent of WBC count Hemoglobin Parameters: HGB -- Hemoglobin concentration MCH -- Mean Corpuscular Hemoglobin MCHC -- Mean Corpuscular Hemoglobin Concentration</p>
<p>*BAND -- Band Neutrophil absolute count *%BD -- Band Neutrophil percent *IMMG -- Immature Granulocyte absolute count *%IG -- Immature Granulocyte percent *BLST -- Blast absolute count *%BL -- Blast percent *VARL -- Variant Lymphocyte absolute count *%VL -- Variant Lymphocyte percent</p>	<p>Reticulocyte Parameters: RETC -- Reticulocyte concentration %R -- Reticulocyte percent of RBC count *IRF -- Immature Reticulocyte Fraction Platelet Parameters: PLT -- Platelet Count MPV -- Mean Platelet Volume *PDW -- Platelet Distribution Width *PCT -- Plateletcrit</p>

* 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 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 has similarities to one or more of the methods of determination for hemagram and automated WBCs differential parameters used by the following hematology analyzers: Coulter[®] Counters (Model ZBI, Hemoglobinometer, S-Plus Series and STKS); Sysmex[™] NE Series; Technicon H*1[™] Series; Becton Dickinson FACScan[™], and Abbott CELL-DYN[®] 3000 Series. The CELL-DYN[®] 4000 System has similarities to one or more of the methods of determination for reticulocyte enumeration used by the Becton Dickinson FACScan[™] and the Sysmex[™] R-3000.

The Coulter[®] Counters (Model ZBI, S-Plus Series and STKS), Abbott CELL-DYN[®] 3000 Series, and the CELL-DYN[®] 4000 System are similar in that they use impedance for counting and sizing RBCs and PLTs. The CELL-DYN 4000 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 are similar 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.

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 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 uses an Argon-ion laser that allows fluorescent data to be collected simultaneously with the optical scatter data. This change enables the CELL-DYN 4000 to count and classify WBCs, NRBCs, and fragile (nonviable) WBCs. The Becton Dickinson FACScan[™] and the CELL-DYN[®] 4000 System both 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, and the CELL-DYN[®] 4000 System 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 and 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 is different in that it automatically dilutes the

specimen with a fast acting proprietary dye which requires no incubation prior to measurement.

Equivalency Data: The data compiled to support the claim that the CELL-DYN[®] 4000 System is substantially equivalent to the Abbott CELL-DYN[®] 3500 System includes accuracy, precision, linearity, and carryover.

The data supports the claim that the CELL-DYN[®] 4000 System is substantially equivalent to the Abbott CELL-DYN[®] 3500 System for the hemagram and automated WBC differential parameters and to the Becton Dickinson FACScan[™] for the reticulocyte parameters. The accuracy, precision, and linearity data shows performance to manufacturer's specifications.

Conclusion: The CELL-DYN[®] 4000 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[®] 3500 System and the Becton Dickinson FACScan[™].

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