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510(k) SUMMARY
CELL-DYN®3000 Multi-Parameter Automated Hematology Analyzer

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING A
SUBSTANTIALLY EQUIVALENT DETERMINATION

The following information for the Cell-Dyn® 3000 Hematology Analyzer constitutes data supporting a substantially equivalent determination.

Substantial equivalence has been demonstrated between the Cell-Dyn 3000 and the Coulter® ZBI (marketed prior to May 1976), Coulter Hemoglobinometer (marketed prior to May 1976), the Coulter Model S (marketed prior to May 1976), the Coulter Model S Plus IV, all included in Premarket Notification #K890491, and the Cell-Dyn® 3500, Premarket Notification K#913305/A.

Intended Use

The Cell-Dyn 3000 is a multi-parameter, hematology analyzer designed for In-Vitro diagnostic use in clinical laboratories.

Device Description

The Cell-Dyn 3000 is a table-top analyzer consisting of the main analyzer, data station, and printer. An optional Sample Loader can be attached to the analyzer to transport samples in racks for automated processing.

The instrument has two sampling modes: Open Sample Aspiration Mode and Closed Sample Aspiration Mode. The instrument has the capability of diluting a sample for a CBC including a 5-part WBC differential for a total of 20 parameters. The 20 reportable parameters are as follows:

White blood cells (WBC), red blood cells (RBC), platelets (PLT), percent of neutrophils (%N), number of neutrophils (NEU), percent of lymphocytes (%L), number of lymphocytes (LYM), percent of monocytes (%M), number of monocytes (MONO), percent of eosinophils (%E), number of eosinophils (EOS), percent of basophils (%B), number of basophils (BASO), hemoglobin (HGB), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red cell distribution width (RDW) and mean platelet volume (MPV).

Principles of Operation

The Shear valve isolates a precise volume of whole blood by means of a shearing action as the front and rear sections rotate. The aspirated blood is isolated in three separate segments - one for the WBC dilution, one for the RBC/PLT dilution and one for the HGB dilution. The WBC segment is diluted with the sheath reagent. The RBC/PLT segment is diluted with the diluent and the HGB segment is diluted with diluent and hemoglobin lyse reagent is added to lyse the RBCs.

The instrument then measures, using the electrical impedance method, the number and size of cells present per volume of whole blood for RBC and PLT. It measures, using laser optical methods, the number of WBCs present per volume of whole blood. It derives, using light scattering measurements, values for: %N, %L, %M, %E and %B. It derives, using electrical impedance measurements, values for: MCV, RDW, MPV, PDW, and calculates, using appropriate measured or derived data, the values for: NEU, LYM, MONO, EOS, BASO, HCT, MCH, MCHC and PCT.

Similarities and Differences

The methods of determination are those used by the Coulter® ZBI, Coulter, Hemoglobinometer, Coulter Model S, Coulter Model S Plus Series, the Cell-Dyn® 3500 and the manual microscopic differential count. These methods collectively perform one or more of the determinations which are combined in the Cell-Dyn® 3000.

The Cell-Dyn 3000 differs from the above instruments in that it uses an optical method to provide the WBC count and differential. Additionally, the Cell-Dyn® 3000 monitors the optical WBC count to generate the various WBC flags.

Equivalency Data

The data compiled to support the claim that the Cell-Dyn® 3000 is substantially equivalent to the Cell-Dyn 3500 includes accuracy, precision, linearity and carryover. The Cell-Dyn® 3000 WBC differential has been compared to the NCCLS reference microscopic manual differential method for accuracy.

The accuracy, precision and linearity data shows performance to manufacturer's specifications. The data supports our claim that the Cell-Dyn® 3000 is substantially equivalent to the Cell-Dyn® 3500. The modifications of the instrument are intended to enhance the safety and effectiveness of the Cell-Dyn® 3000 and demonstrate substantial equivalence to the Cell-Dyn 3500, #K913305/A.

Conclusion

In conclusion, the Cell-Dyn 3000 update shows an evolution of the technology used that is similar to the technology used in the Coulter ZBI, Coulter Hemoglobinometer, Coulter Model S and Coulter S Plus series and shows substantial equivalence to the technology used in the the Cell-Dyn® 3500.

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