

JUN 29 1998

CELL-DYN® 4000 ImmunoPlt™ (CD61)

K981342

510(k) Notification

510(k) SUMMARY

CELL-DYN®4000 Multi-Parameter Automated Hematology Analyzer with Immunological (CD61) Platelet Count

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® 4000 System Hematology Analyzer with ImmunoPlt™ (CD61) Assay, constitutes data supporting a substantially equivalent determination.

The methods of determination are those used by the CELL-DYN®4000 System and the manual phase platelet method. These methods collectively perform one or more of the determinations which are combined in the CELL-DYN® 4000 System with ImmunoPlt (CD61) Assay.

Intended Use

The CELL-DYN 4000 System with ImmunoPlt (CD61) Assay is a multi-parameter, automated, hematology analyzer designed for *in-vitro* diagnostic use in clinical laboratories.

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 System with ImmunoPlt (CD61) Assay is designed to analyze EDTA-anticoagulated whole blood specimens and report the hematological parameters shown in the table on the following page.

CELL-DYN®4000 System with ImmunoPlt™ (CD61) Assay:

<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</p> <p>*vWF -- Viable White Cell fraction</p>	<p>Red Blood Cell Parameters: RBC -- Red Blood Cell or erythrocyte count *RBCo -- RBC Optical count RBCi -- RBC Impedance 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</p> <p>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 *IG -- Immature Granulocyte absolute count *%IG -- Immature Granulocyte percent *BLST -- Blast absolute count *%BL -- Blast percent *MONe -- non-Blast Monocyte absolute count *%Me -- non-Blast Monocyte percent *LYMe -- non-Blast, non-variant Lymphocyte absolute count *Le -- non-Blast, non-variant Lymphocyte 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</p> <p>Platelet Parameters: PLT -- Platelet Count CD61 -- ImmunoPlt (CD61) Count PLTo -- Platelet Optical count *PLTi -- Platelet Impedance count MPV -- Mean Platelet Volume *PLTs -- Small Platelets *PLTI -- Large Platelets *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, with Focused Flow Impedance, and Absorption Spectrophotometry. The ImmunoPlt (CD61) count is derived from the light scatter and fluorescence of the mAb labeled Platelets. 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 ImmunoPlt (CD61) count, the blood is mixed with the FITC-bound Monoclonal Antibody, CD61. Laser optical scatter is measured as described above and green fluorescence (FL1) is measured.

For the hemoglobin parameters, whole blood is diluted with a cyanide free reagent and the hemoglobin is measured optically by absorbance (540 nm). 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 and the CELL-DYN® 4000 System with ImmunoPlt™ (CD61) Assay are similar in that they use Focused Flow Impedance to count and size RBCs and PLTs, they use Injection Metering to measure RBCs and PLTs optically, and they compare optical and impedance data as an internal quality check. The CELL-DYN® 4000 System with GD61 ImmunoPlt (CD61) Assay is different from the CELL-DYN® 4000 System in that it counts CD61 labeled platelets and measures the results optically and by fluorescence.

Equivalency Data

The data compiled supports the claim that the CELL-DYN® 4000 System with ImmunoPlt (CD61) Assay is substantially equivalent to the Abbott the CELL-DYN® 4000 System and to phase microscopy (for platelet counts < 50 K/μL). The data includes accuracy, precision, linearity, and carryover and shows performance to manufacturer's specifications.

Conclusion

The CELL-DYN® 4000 System with ImmunoPlt™ (CD61) Assay shows an evolution of the technologies used on one or more of the currently available analyzers to count, size, and classify blood cells and their related parameters, and more specifically, to the technologies used on the Abbott CELL-DYN® 4000 System.

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

Janice E. Brown
Regulatory Affairs Manager
Abbott Diagnostics
5440 Patrick Henry Drive
Santa Clara, CA 95054

Phone: 408 567-3521
Fax: 408 982-4863



JUN 20 2012

Abbott Laboratories
c/o Ms. Janice E. Brown
Regulatory Affairs Manager
5440 Patrick Henry Drive
Santa Clara, CA 95054

Re: k981342

Trade/Device Name: CELL-DYN® 4000 ImmunoPlt (CD61) Assay
Regulation Number: 21 CFR §864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: April 10, 1998
Received: April 13, 1998

Dear Ms. Brown:

This letter corrects our substantially equivalent letter of June 29, 1998.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical

device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

for 
Maria M. Chan, Ph.D.

Director

Division Immunology and Hematology Devices

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

510(k) Number (if known): K981342
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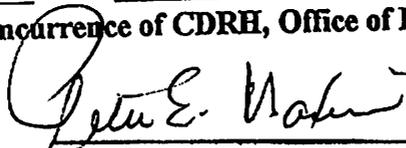
Device Name: CELL-DYN® 4000 System with ImmunoPlt™ (CD61) Assay

Indications For Use:

The CELL-DYN® 4000 System with ImmunoPlt (CD61) Assay is a fully automated hematology analyzer, including reporting of the ImmunoPlt (CD61) count, intended for *in-vitro* diagnostic use in the clinical laboratory of a hospital, medical clinic, or reference laboratory.

(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 K981342

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)