March 15, 2019

Abbott Laboratories
Madhu Gill
Regulatory Affairs Specialist
4551 Great America Pkwy
Santa Clara, California 95054

Re: K190294
Trade/Device Name: CELL-DYN Emerald 22 AL System
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: February 8, 2019
Received: February 11, 2019

Dear Madhu Gill:

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 application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Takeesha Taylor-bell -S

Takeesha Taylor-Bell
Chief, Hematology Branch
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

For

Lea Carrington
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190294

Device Name
CELL-DYN Emerald 22 AL System

Indications for Use *(Describe)*
The CELL-DYN Emerald 22 AL System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro diagnostic use in clinical laboratories for enumeration of the following parameters: WBC, LYM%, LYM #, MON %, MON #, NEU%, NEU #, EOS%, EOS #, BAS%, BAS #, RBC, HCT, MCV, RDW, HGB, MCH, MCHC, PLT, MPV in K2EDTA anti-coagulated whole blood.

The CELL-DYN Emerald 22 AL is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act 1990 and 21CFR 807.92

The assigned 510(k) number is: K190294

I	**Submitter**	Abbott Laboratories 4551 Great America Pkwy Santa Clara, CA 95054 Phone: (408) 567-3701; Fax: (408) 567-3657 Contact Person: Madhu Gill Date Prepared: February 12, 2019
II	**Device**	Trade Name: CELL-DYN Emerald 22 AL System Common Name: Automated Hematology Analyzer Device Classification: Class II GKZ – Automated Differential Cell Counter (21 CFR 864.5220) Trade Marks: CELL-DYN Emerald is a trademark of Abbott Laboratories
III	**Predicate Device and 510(k) number**	The predicate device is CELL-DYN Emerald 22 system, K110381, cleared December 22, 2011.

IV. Intended Use/ Indications for Use

The CELL-DYN Emerald 22 AL System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro diagnostic use in clinical laboratories for enumeration of the following parameters: WBC, LYM%, LYM #, MON%, MON #, NEU%, NEU #, EOS%, EOS #, BAS%, BAS #, RBC, HCT, MCV, RDW, HGB, MCH, MCHC, PLT, MPV in K_2EDTA anti-coagulated whole blood. The CELL-DYN Emerald 22 AL is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.

V. Device Description

The CELL-DYN Emerald 22 AL analyzer is a bench top analyzer, consisting of the main analyzer, autoloader module, and touch screen display. Sample analysis may be performed in open or closed mode. The CELL-DYN Emerald 22 AL is equipped with a sample loader that provides continuous automated closed mode sampling for up to 50 closed tube samples, one at a time. The analyzer is also equipped with a tube holder assembly that allows the use of open tube sampling.

The CELL-DYN Emerald 22 AL is designed to automatically perform the following:

a) Aspirate and dilute whole blood
b) Count, size and classify cells present in a whole blood specimen
c) Measure the hemoglobin concentration of a whole blood specimen
d) Analyze the raw data that is collected
e) Output results to the display, printer and laboratory information system

Three types of measurements are used to count, size and classify blood cells and to measure hemoglobin. The three types of measurements are:

a) Electrical Impedance Counting
b) Absorption Spectrophotometry
c) Optical Flow Cytometry

The electrical impedance counting is used for WBC, RBC and PLT measurements. The absorption spectrophotometry is used for HGB measurement. The optical flow cytometry is used

for WBC differential. HCT is derived from the volume of the RBCs that are counted during the measurement cycle.

The CELL-DYN Emerald 22 AL provides the following parameters:

White Blood Cell Parameters

- WBC White Blood Cell or leukocyte count
- LYM % Lymphocyte percent*
- LYM # Lymphocyte absolute number*
- MON % Monocyte percent*
- MON # Monocyte absolute number*
- NEU % Neutrophil percent*
- NEU # Neutrophil absolute number*
- EOS% Eosinophil percent*
- EOS # Eosinophil absolute number*
- BAS % Basophil percent*
- BAS # Basophil absolute number*

  ** WBC differential parameters are measured and reported in DIF mode only.*

Red Blood Cell Parameters

- RBC Red Blood Cell or erythrocyte count
- HCT Hematocrit
- MCV Mean Cell Volume
- RDW Red Blood Cell Distribution Width

Hemoglobin Parameters

- HGB Hemoglobin concentration
- MCH Mean Cell Hemoglobin
- MCHC Mean Cell Hemoglobin Concentration

Platelet Parameters

- PLT Platelet count
- MPV Mean Platelet Volume

VI. Summary of Substantial Equivalence:

Table 4.1 below compares the CELL-DYN Emerald 22 AL with the predicate device, CELL-DYN Emerald 22 (K110381).

Table 4.1: Similarities and differences between CELL-DYN Emerald 22 AL System and CELL-DYN Emerald 22 System (K110381).

Item	**Predicate device, CELL-DYN Emerald 22 (K110381)**	**Modified device, CELL-DYN Emerald 22 AL**
Similarities		
Intended Use/ Indications for Use	The CELL-DYN Emerald 22 System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro diagnostic use in clinical laboratories for enumeration of the following parameters: WBC, LYM%, LYM #, MON%, MON #, NEU%, NEU #, EOS%, EOS #, BAS%, BAS #, RBC, HCT, MCV, RDW, HGB, MCH, MCHC, PLT, MPV in K_2EDTA anti-coagulated whole blood. The CELL-DYN Emerald 22 is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.	The CELL-DYN Emerald 22 AL System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro diagnostic use in clinical laboratories for enumeration of the following parameters: WBC, LYM%, LYM #, MON%, MON #, NEU%, NEU #, EOS%, EOS #, BAS%, BAS #, RBC, HCT, MCV, RDW, HGB, MCH, MCHC, PLT, MPV in K_2EDTA anti-coagulated whole blood. The CELL-DYN Emerald 22 AL is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.

Item	**Predicate device, CELL-DYN Emerald 22 (K110381)**	**Modified device, CELL-DYN Emerald 22 AL**
WBC differential	5-part differential	5-part differential
Parameters	White Blood Cells: WBC LYM% LYM # MON% MON # NEU% NEU # EOS% EOS # BAS% BAS # Red Blood Cells: RBC HCT MCV RDW Hemoglobin: HGB MCH MCHC Platelets: PLT MPV	White Blood Cells: WBC LYM% LYM # MON% MON # NEU% NEU # EOS% EOS # BAS% BAS # Red Blood Cells: RBC HCT MCV RDW Hemoglobin: HGB MCH MCHC Platelets: PLT MPV

Item	**Predicate device, CELL-DYN Emerald 22 (K110381)**	**Modified device, CELL-DYN Emerald 22 AL**
Technology	Optical differential by LED 455nm Electric impedance Spectrophotometry by LED 555nm	Optical differential by LED 455nm Electric impedance Spectrophotometry by LED 555nm
Sample Type	K_2EDTA anticoagulated human whole blood for all parameters	K_2EDTA anticoagulated human whole blood for all parameters
Reagents	CELL-DYN Emerald 22 Diluent CELL-DYN Emerald 22 Lyse CELL-DYN Emerald 22 Easy Cleaner	CELL-DYN Emerald 22 Diluent CELL-DYN Emerald 22 Lyse CELL-DYN Emerald 22 Easy Cleaner
Controls and Calibrator	CELL-DYN 22 Plus Control CELL-DYN 22 Plus Calibrator	CELL-DYN 22 Plus Control CELL-DYN 22 Plus Calibrator
Histograms	WBC, PLT, RBC	WBC, PLT, RBC
Scatterplot	WBC	WBC
Alphanumeric Specimen ID	Feature Available	Feature Available
Differences		
Sample loading mechanism	Individual uncapped tube samples are manually presented to the sample probe for aspiration.	Autoloader assembly was added to allow for loading up to 50 closed tube samples at a time. The autoloader assembly includes the following modules/components: - Sample racks - Loader - Transfer/mixer - Unloader - Internal bar code reader - Frames and covers

Item	Predicate device, CELL-DYN Emerald 22 (K110381)	Modified device, CELL-DYN Emerald 22 AL
Printed Circuit Board Assembly (PCBA) (System Board)	The PCBA controls three motors. Two motors are used to the drive sampling module and one to drive syringes. The micro-processor is CPU 5272. The CPU compiler is Metrowerks.	A new PCBA that controls seven motors was implemented. The additional four motors are to drive the following autoloader functions: load, transfer, mix, and eject. The new CPU is Phytec CPU Freescale i.MX27, ARM926EJ, 400MHz+. The CPU complier is Codeblocks + gcc. The source code was adapted for the new CPU and compiler.
Instrument size	Height: 13.8 inches (35 cm) Width: 9.8 inches (25 cm) Depth: 13.8 inches (35 cm) Weight: ~24.2 lbs. (11 kg)	Height: 16.1 inches (41 cm) Width: 19.7 inches (50 cm) Depth: 17.0 inches (43 cm) Weight: ~55 lbs. (25 kg)
Sampling module	The sampling module utilizes a blunt aspiration sampling probe. Components of the sample module include: - Sampling probe - Probe rinsing head - Probe motor and belt	The sampling module contains the following modifications to allow for cap piercing in closed mode and needle cleaning: - Trocar type needle - Needle rinsing head - Needle motor and belt
Open tube operation	Open tube sampling is performed by manually presenting an opened sample tube to the sampling probe for aspiration.	Tube Holder assembly was added to hold the opened sample tube for sample aspiration to prevent needle exposure. The addition of the tube holder assembly includes: - Fixed station and sensors - Open tube sheath - Open tube holder

Item	Predicate device, CELL-DYN Emerald 22 (K110381)	Modified device, CELL-DYN Emerald 22 AL
Source of vacuum for cleaning	The sampling probe is cleaned via the vacuum created by the waste syringes.	Needle cleaning is managed by a stronger vacuum source created by a pump. An in-line filter was added to prevent particles from entering the pump.
Dilution and Counting module	Diluent for RBC/PLT dilution and for cleaning the needle share the same flow path. The inner diameter for the drain hole of the chamber is 1.2mm.	The RBC/PLT diluent path for dilution was modified using an additional valve to separate diluent flow to the rinsing head and the RBC/PLT chamber. The inner diameter for the waste draining hole was increased from 1.2 to 1.6 mm to accommodate for cap coring.
Incubation duration	Incubation time for Resistive count is 15.5 seconds and for Optic count is 20.5 seconds.	Incubation time for Resistive count is 18.5 seconds and for Optic count is 24 seconds. The longer incubation time is the consequence of the change in diluent path.
Dead volume for sampling	There is no minimum volume requirement.	The minimum volume of sample required is 500 uL for standard tubes and 250 uL for capillary tubes.
Sample aspiration volume	17 uL of blood sample is aspirated during sampling cycle and used for testing.	21 uL of blood sample is aspirated during sampling cycle, and 17 uL is used for testing. The extra volume of blood is discarded prior to dilution. The dilution ratio is the same as the predicate device, CELL-DYN Emerald 22.

Item	Predicate device, CELL-DYN Emerald 22 (K110381)	Modified device, CELL-DYN Emerald 22 AL
Reagent consumption volume	Information on reagent consumption is provided in the CELL-DYN Emerald 22 Operator's Manual (Section 4, Table 4.4).	Information on reagent consumption is provided in the CELL-DYN Emerald 22 AL Operator's Manual (Section 4, Table 4.5). Additional volume of reagent is needed for the cleaning cycle/process, compared to CELL-DYN Emerald 22.
Fluidic cycles	No cap piercing and needle cleaning with pump.	The fluidic cycles were adapted to accommodate the changed fluidic configuration required for cap piercing.
Throughput	Throughput is 45 per hour (open tube). Sample cycle takes 74 seconds to complete in open mode.	Throughput is 40 per hour (open tube). Sample cycle takes 76 seconds to complete in open tube mode due to the additional cleaning of the needle, as well as the steps needed for the use of the added tube holder. Throughput is 40 per hour (closed tube). Sample cycles takes 90 seconds to complete in closed mode due to additional tube piercing process.
USB ports	No USB hub. 2 USB ports in the back of the instrument for USB thumb drive and printer.	The USB hub PCB provides 3 USB ports located for convenience in the front of the instrument for external thumb drive and keyboard connections.

Item	Predicate device, CELL-DYN Emerald 22 (K110381)	Modified device, CELL-DYN Emerald 22 AL
		One USB port is located in the back of the instrument and used for printer connection only.
User Interface	User Interface was designed for a smaller screen size. 5.4” LCD touch screen with physical numeric keypad on the front.	User Interface was designed for a bigger screen size that allows displaying of more data and ease of navigation. 8.4” LCD touch screen with on screen alpha numeric keypad. Action buttons are rearranged. New autoloader and worklist screens. There is no physical keypad on the front.
Operating system	The system utilizes operating system OSE Epsilon.	The system utilizes operating system OSE Delta.
Fluidics interface	Commands for open tube fluidic configuration.	Same commands for open tube fluidic configuration and new commands to manage the pump functionality.
Patient ID and demographic information management	Single input of patient samples at a time.	A worklist is provided to process a batch of patient samples manually or via the Laboratory Information System (LIS).
Rack management	No rack management.	Added rack management module
Tube holder management	No tube holder management.	Added module to detect the presence of open tube assembly and adjust sampling depth in tubes.

Item	Predicate device, CELL-DYN Emerald 22 (K110381)	Modified device, CELL-DYN Emerald 22 AL
Flagging	Flags are detailed in the CELL-DYN Emerald 22 Operator's Manual, Section 3, Sub-section Instrument Alarms, Operational Alerts, and Parameter Data Flags	Same flagging rules. HGB flagging bug was fixed. PLT suspicion flag was added to address potential carryover due to the grooves in the new Trocar needle.

VII. Summary of Analytical Performance

To demonstrate that the CELL-DYN Emerald 22 AL System is substantially equivalent to the CELL-DYN Emerald 22 System, the following non-clinical design verification analyses were performed and evaluated:

a. Background
b. Carryover
c. Linearity
d. Short-Term Imprecision
e. Long-Term Imprecision
f. Method Comparison
g. Blood Tube Type Study
h. Mode-to-Mode Equivalency
i. Data Invalidation Clogging Rate

Results of this testing demonstrated substantial equivalence between the CELL-DYN Emerald 22 AL System and the CELL-DYN Emerald 22 System with respect to analytical performance and that the addition of the sample loader module does not impact functional performance.

VIII. Summary of Clinical Testing

Not applicable.

IX. Conclusion:

The CELL-DYN Emerald 22 AL and its predicate device, CELL-DYN Emerald 22 (K110381), have the same Intended Use, Indications for Use, fundamental technology, principles of operation, specimen type, Analytical Measurement Range (AMR), reagents, calibrator, controls, parameters and comparable performance characteristics. The modifications consist of a larger analyzer with a slightly slower throughput, slightly larger sample aspiration volumes, slightly larger incubation duration, different operating system and user interface. Analytical performance and software verification, and human factor validation testing were conducted to characterize the performance of the CELL-DYN Emerald 22 AL and all predetermined acceptance criteria were met. The results of this testing demonstrated that the device is as safe, as effective, and performs as well as or better than the CELL-DYN Emerald 22 and is suitable for the labeled indication for use. Predicate device clinical validation testing was used for Emerald 22 AL as no variation in performance was found between the predicate and modified device. The difference in technological characteristics between the predicate device and CELL-DYN Emerald 22 AL do not raise different question of safety and effectiveness.