November 22, 2023

Beckman Coulter, Inc
Stephanie Harlacz
Staff Regulatory Affairs Specialist
11800 SW 147 Ave
Miami, Florida 33196

Re: K232600
Trade/Device Name: DxFLEX Flow Cytometer; ClearLLab 10C Panels
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: OYE, PWD
Dated: August 25, 2023
Received: August 28, 2023

Dear Stephanie Harlacz:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232600

Device Name

DxFLEX Flow Cytometer;
ClearLLab 10C Panels

Indications for Use *(Describe)*

The DxFLEX Flow Cytometer is intended for use as an in vitro diagnostic device for immunophenotyping using up to ten fluorescent detection channels using three lasers (488 nm, 638 nm and 405 nm) and two light scatter detection channels. It is intended for use with in vitro diagnostic (IVD) assays and software that are indicated for use with the instrument

The ClearLLab 10C Panels are intended for in vitro diagnostic use for qualitative identification of cell populations by multiparameter immunophenotyping on the Navios, Navios EX and DxFLEX flow cytometers. These reagents are used as an aid in the differential diagnosis of hematologically abnormal patients having, or suspected of having, the following hematopoietic neoplasms: chronic leukemia, acute leukemia, non-Hodgkin lymphoma, myeloma, myelodysplastic syndrome (MDS), and/or myeloproliferative neoplasms (MPN). The reagents can be used with peripheral whole blood (collected in K2EDTA, Acid Citrate Dextrose (ACD) or Heparin), bone marrow (collected in K2EDTA, ACD or Heparin) and lymph node specimens. Interpretation of the results should be confirmed by a pathologist or equivalent professional in conjunction with other clinical and laboratory findings.
These reagents provide multiparameter, qualitative results for the surface antigens listed below:
- ClearLLab 10C B Cell Tube: Kappa, Lambda, CD10, CD5, CD200, CD34, CD38, CD20, CD19, CD45
- ClearLLab 10C T Cell Tube: TCRγδ, CD4, CD2, CD56, CD5, CD34, CD3, CD8, CD7, CD45
- ClearLLab 10C M1 Cell Tube: CD16, CD7, CD10, CD13, CD64, CD34, CD14, HLA-DR, CD11b, CD45
- ClearLLab 10C M2 Cell Tube: CD15, CD123, CD117, CD13, CD33, CD34, CD38, HLA-DR, CD19, CD45

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.

510(k) Summary for
ClearLLab 10C Reagents on DxFLEX Flow Cytometer

510(k) Owner / Submitter Information

Name: Beckman Coulter Inc.
Address: 11800 SW 147th Ave., Miami, FL 33196
Phone #: (305) 563-0116
Contact Person: Stephanie Harlacz
Email Address: smharlacz@beckman.com
Date Submitted: 25 August 2023

Device Information

Trade Name: **DxFLEX Flow Cytometer**
Common Name: DxFLEX Flow Cytometer
Classification Name: Automated differential cell counter (21 CFR 864.5220)
Classification: Class II
Product Code: OYE
Panel: Hematology

Trade Name: **ClearLLab 10C (T), ClearLLab 10C (B), ClearLLab 10C (M1), ClearLLab (M2)**
Common Name: ClearLLab Reagents
Classification Name: Flow Cytometric Test System for Hematopoietic Neoplasms (21 CFR 864.7010)
Classification: Class II
Product Code: PWD
Panel: Hematology

Predicate Device Information

Predicate Product	510(k) Number	Date Cleared	Classification	21 CFR	Product Code
Navios EX Flow Cytometer	K183592	03/21/2019	Class II	864.5220	OYE
ClearLLab 10C Reagent System	K183592	03/21/2019	Class II	864.7010	PWD

Device Description

The ClearLLab 10C Reagent System is currently cleared on the Navios EX Flow cytometer under K183592. Beckman Coulter has developed the DxFLEX Flow Cytometer, a next generation flow cytometer that offers enhanced performance in terms of optics and electronics, as well as more convenient installation and operation. The indications for use of the ClearLLab 10C Reagent System will be expanded to include its use on the DxFLEX Flow Cytometer. Furthermore, the indications for use will be clearly stated on labeling. The intended use of the ClearLLab 10C Reagent System will not be modified.

ClearLLab 10C Reagent System components that are included with use on the DxFLEX Flow Cytometer:

- DxFLEX Flow Cytometer [3 laser/10 color configuration] [New]
- DxFLEX Daily QC Fluorospheres [New]
- ClearLLab 10C Panels [B, T, M1 and M2] [Modification to Existing]
- ClearLLab Compensation Kit [Modification to Existing]
- ClearLLab Compensation Beads [Modification to Existing]
- ClearLLab Control Cells, normal and abnormal [Modification to Existing]
- Kaluza C data analysis software [Existing]
- IOTest 3 Fixative Solution [Existing]
- IOTest 3 Lysing Solution [Existing]

The ClearLLab 10C Reagent System is run on Beckman Coulter's DxFLEX Flow Cytometer (3 Laser/10 Color configuration]. The DxFLEX Flow Cytometer includes the hardware and CytExpert for DxFLEX software. It requires off-line manual sample processing and use of the accompanying lysing reagent. As part of the ClearLLab 10C Reagent System, to allow proper utilization of this application, the indications for the DxFLEX flow cytometers include ten fluorescent detection channels (FL1-FL10) and three laser configurations (blue, red and violet).

As with the workflow on the predicate system, LMD data analysis is performed manually using the Kaluza C Analysis Software. This Analysis Software package is supplied separately from the DxFLEX and must be installed on an independent computer workstation for off-line analysis of listmode files generated on the flow cytometer with the associated reagents and cytometer system software package, including Control Cell QC data and sample data analysis. The CytExpert for DxFLEX software is NOT be recommended for analysis use with this application (Note that QC data DxFLEX Daily QC Fluorospheres and Compensation products will continue to be analyzed using the on-board instrument software).

Kaluza C Software is a software tool designed to work with *.fcs and *.lmd files generated from flow cytometers. The advantages of using the Kaluza C over the CytExpert for DxFLEX software are listed below:

- Powerful processing speed allows fast analysis of listmode data, including real-time updating of gating and compensation
- Plot displays are more versatile allowing linear, logarithmic and 'Logicle' (linear/log hybrid) axes as well as configurable scaling and zooming options
- Range of compensation options
- QC reporting includes Levey-Jennings plots and highlighted pass/fail criteria on results displays

Preset Kaluza C analysis templates for the ClearLLab 10C reagent system will be provided. The total WBC gate is defined in the histogram of SS vs. CD45-KO525-A by the inclusion of all CD45+ events with low, medium and high Side Scatter after the exclusion of the cells that were compromised and/or aggregated. A subsequent histogram defines specific leukocyte subset such as lymphocytes, monocytes, granulocytes. The low SS/bright CD45+ population identifies lymphocytes. Applicable markers are then displayed in subsequent histograms gated on lymphocytes. This process is repeated for mid SS/medium CD45+ populations to identify monocytes and for high SS/medium CD45+ to identify granulocytes.

Intended Use:

DxFLEX Flow Cytometer

The DxFLEX Flow Cytometer is intended for use as an in vitro diagnostic device for immunophenotyping using up to ten fluorescent detection channels using three lasers (488 nm, 638 nm, and 405 nm) and two light scatter detection channels. It is intended for use with in vitro diagnostic (IVD) assays and software that are indicated for use with the instrument.

ClearLLab 10C Panels

The ClearLLab 10C Panels are intended for in vitro diagnostic use for qualitative identification of cell populations by multiparameter immunophenotyping on the DxFLEX flow cytometers. These reagents are used as an aid in the differential diagnosis of hematologically abnormal patients having, or suspected of having, the following hematopoietic neoplasms: chronic leukemia, acute leukemia, non-Hodgkin lymphoma, myeloma, myelodysplastic syndrome (MDS), and/or myeloproliferative neoplasms (MPN). The reagents can be used with peripheral whole blood (collected in K_2EDTA, Acid Citrate Dextrose (ACD) or Heparin), bone marrow (collected in K_2EDTA, ACD or Heparin) and lymph node specimens. Interpretation of the results should be confirmed by a pathologist or equivalent professional in conjunction with other clinical and laboratory findings. These reagents provide multiparameter, qualitative results for the surface antigens listed below:

- ClearLLab 10C B Cell Tube: Kappa, Lambda, CD10, CD5, CD200, CD34, CD38, CD20, CD19, CD45
- ClearLLab 10C T Cell Tube: TCRγδ, CD4, CD2, CD56, CD5, CD34, CD3, CD8, CD7, CD45
- ClearLLab 10C M1 Cell Tube: CD16, CD7, CD10, CD13, CD64, CD34, CD14, HLA-DR, CD11b, CD45
- ClearLLab 10C M2 Cell Tube: CD15, CD123, CD117, CD13, CD33, CD34, CD38, HLA-DR, CD19, CD45

Technological Characteristics Comparisons, Subject System to Predicate

Characteristic	ClearLLab 10C Reagent System on Navios EX flow cytometer (K183592) - Predicate	ClearLLab 10C Reagent System on DxFLEX flow cytometer
FDA product code for ClearLLab 10C Panels	PWD	PWD
Intended Use	*In vitro* diagnostic device for immunophenotyping	*In vitro* diagnostic device for immunophenotyping
Indications for Use	Intended for in vitro diagnostic use as a panel for qualitative identification of various cell populations by immunophenotyping on the Navios and Navios EX flow cytometers. These reagents are used as an aid in the differential diagnosis of hematologically abnormal patients having the following hematopoietic neoplasms: chronic leukemia, acute leukemia, non-Hodgkin lymphoma, myeloma, myelodysplastic syndrome (MDS), and/or myeloproliferative neoplasms (MPN). The reagents can be used with peripheral whole blood (collected in K_2EDTA, ACD or Heparin), bone marrow (collected in K_2EDTA, ACD or Heparin) and lymph node specimens for immunophenotyping. The results should be interpreted by a pathologist or equivalent in conjunction with other clinical and laboratory findings.	SAME (with the exception of cytometer) Intended for in vitro diagnostic use as a panel for qualitative identification of various cell populations by immunophenotyping on the Navios, Navios EX and DxFLEX flow cytometers. These reagents are used as an aid in the differential diagnosis of hematologically abnormal patients having the following hematopoietic neoplasms: chronic leukemia, acute leukemia, non-Hodgkin lymphoma, myeloma, myelodysplastic syndrome (MDS), and/or myeloproliferative neoplasms (MPN). The reagents can be used with peripheral whole blood (collected in K_2EDTA, ACD or Heparin), bone marrow (collected in K_2EDTA, ACD or Heparin) and lymph node specimens for immunophenotyping. The results should be interpreted by a pathologist or equivalent in conjunction with other clinical and laboratory findings.

Characteristic	ClearLLab 10C Reagent System on Navios EX flow cytometer (K183592) - Predicate				ClearLLab 10C Reagent System on DxFLEX flow cytometer
Reagent Panels	**B panel**	**T panel**	**M1 panel**	**M2 panel**	ALL MARKERS ARE THE SAME
	KAPPA	TCRγδ	CD16	CD15	
	LAMBDA	CD4	CD7	CD123	
	CD10	CD2	CD10	CD117	
	CD5	CD56	CD13	CD13	
	CD200	CD5	CD64	CD33	
	CD34	CD34	CD34	CD34	
	CD38	CD7	CD14	CD38	
	CD20	CD8	HLA-DR	HLA-DR	
	CD19	CD3	CD11b	CD19	
	CD45	CD45	CD45	CD45	
Reagent Form	Dry unitized form (one test / panel)				SAME
Storage Conditions	Room Temperature				SAME
Set-up Reagents *Optical and Fluidics Alignment*	Flow-Check Pro Fluorospheres				SIMILAR DxFLEX Daily QC Fluorospheres Same function. Designed to be used on 10 channels of the DxFLEX flow cytometer
Set-up Reagents *Standardization*	Flow-Set Pro Fluorospheres				SIMILAR DxFLEX Daily QC Fluorospheres The standardization for the ClearLLab 10C Reagent System on the DxFLEX Flow Cytometer is performed with the same reagent and during the same step as the optical alignment and fluidics verification.

<table>
<tr><th>Characteristic</th><th>ClearLLab 10C Reagent System on Navios EX flow cytometer (K183592) - Predicate</th><th>ClearLLab 10C Reagent System on DxFLEX flow cytometer</th></tr>
<tr><td></td><td></td><td>DxFLEX Daily QC Fluorospheres have target values assigned to monitor optical alignment and fluidics that are also used as an aid in standardizing forward scatter, side scatter, and fluorescence detectors on the DxFLEX Flow Cytometer.</td></tr>
<tr><td>Lyse and Fixation</td><td>IOTest 3 Fixative Solution
IOTest 3 Lysing Solution</td><td>SAME</td></tr>
<tr><td>Sample Preparation</td><td>Wash and prepare samples manually</td><td>SAME</td></tr>
<tr><td>Sample Age and Prepared Sample Stability</td><td>
<table>
<tr><th colspan="2">Specimen Type</th><th>K₂EDTA</th><th>ACD</th><th>Heparin</th><th>LN (Media)</th></tr>
<tr><td rowspan="2">Whole Blood (WB)</td><td>Specimen Age</td><td>24 hours</td><td>48 hours</td><td>48 hours</td><td></td></tr>
<tr><td>Prepared Sample Age</td><td>5 hours</td><td>5 hours</td><td>5 hours</td><td></td></tr>
<tr><td rowspan="2">Bone Marrow (BM)</td><td>Specimen Age</td><td>24 hours</td><td>48 hours</td><td>48 hours</td><td></td></tr>
<tr><td>Prepared Sample Age</td><td>5 hours</td><td>5 hours</td><td>5 hours</td><td></td></tr>
<tr><td>Lymph Node (LN)</td><td>Prepared Sample Age</td><td colspan="3"></td><td>5 hours</td></tr>
</table>
</td><td>SAME</td></tr>
<tr><td>Color Compensation</td><td>ClearLLab Compensation Kit with ClearLLab Compensation Beads</td><td>SAME, except with labeling changes to include DxFLEX Flow Cytometer only</td></tr>
<tr><td>Control cells</td><td>ClearLLab Control cells (normal and abnormal)</td><td>SAME, except with labeling changes to include DxFLEX Flow Cytometer and assay ranges specific for the DxFLEX Flow Cytometer</td></tr>
</table>

Technological Characteristics Comparisons, Subject Instrument to Predicate

Attribute	Navios EX Flow Cytometer (K183592)	DxFLEX Flow Cytometer
FDA product code for Flow Cytometer	OYE	OYE
Intended Use	The Navios EX Flow Cytometer is intended for use as an in vitro diagnostic device for immunophenotyping using up to ten fluorescent detection channels using three lasers (488 nm, 638 nm, and 405 nm) and two light scatter detection channels. It is intended for use with in vitro diagnostic (IVD) assays and software that are indicated for use with the instrument.	The DxFLEX Flow Cytometer is intended for use as an in vitro diagnostic device for immunophenotyping using up to ten fluorescent detection channels using three lasers (488 nm, 638 nm, and 405 nm) and two light scatter detection channels. It is intended for use with in vitro diagnostic (IVD) assays and software that are indicated for use with the instrument.
Safety Features	Interlocks and mitigation of hazards via software and hardware controls	SAME
Software Architecture	The acquisition software enables the user to acquire data from the instrument and to analyze, display, print and export acquired data. The embedded software resides in the instrument. It controls the instrument functionality including the multi-carousel loader (MCL) for sample introduction. The embedded software controls the instruments' lasers, acquisition system and fluidics. The instrument fluidics aspirates the sample, and performs instrument maintenance functions such as startup/shutdown. The embedded software also captures and provides the data to the workstation for processing.	SAME
Pre-Analytic Features		

Attribute	Navios EX Flow Cytometer (K183592)	DxFLEX Flow Cytometer
System Configuration	• Workstation • PC based workstation running Microsoft Windows 7 and Windows 10 application specific software	SAME, except the workstation only runs Windows 10 Enterprise LTSC 2019
Sample Preparation	Off-board sample preparation following instructions provided with cleared antibody reagent	SAME
Sample Presentation	Sample prepared in dry reagent tube presented in the same tube	SAME
Resuspension of prepared sample prior to introduction to system	Prepared sample is vortex mixed	SAME
Sample Introduction	Tube sampler • Automated presentation with Multi-tube Carousel Loader (MCL) from 32 test tube capacity carousel • Manual presentation into a tube location on a MCL	SAME
Sample Identification	Bar-code reading of carousel position and labeled sample tube. User may also identify samples based on carousel location with a worklist.	SAME
Aspiration Pathway	Same aspiration pathway used for automated and manual presentation	Using peristaltic pump for automatic presentation
Sample Aspiration Probe	Adjustable (by Beckman Coulter field service personnel)	Adjustable (both Beckman Coulter field service personnel and user)
Analytical Features		
Lasers / Driver Boards	Blue (488 nm) • Diode Pumped Solid State (DPSS), **55mW** • 488 nm laser driver board	Blue (488 nm) • Diode Pumped Solid State (DPSS), **50mW** • 488 nm laser driver board

Attribute	Navios EX Flow Cytometer (K183592)	DxFLEX Flow Cytometer
	Red (638 nm) • Diode Pumped Solid State (DPSS), 50 mW • 638 nm laser driver board Violet (405 nm) • Diode Pumped Solid State (DPSS), **80 mW** • 405 nm laser driver board	Red (638 nm) • Diode Pumped Solid State (DPSS), 50 mW • 638 nm laser driver board Violet (405 nm) • Diode Pumped Solid State (DPSS), **85 mW** • 405 nm laser driver board
Forward Angle Light Scatter	• Forward scatter mask • Single lens collimates the light • Band-pass filter passes only 488nm light Diode detector converts light into electrical signals	• Forward scatter mask • Use ellipsoidal mirror to focus the light • Band-pass filter passes only 488nm light Diode detector converts light into electrical signals
Optics	Spherical and cylindrical lenses coupled to the flow cell	Aspherical and cylindrical lenses coupled to the flow cell
Flow Cell	• Channel Size: **140 x 460 microns** • Sheath Flow Pressure: **4 psi** • Thin wall to allow for gel coupling distance • Optics module temperature management hardware: **one** thermoelectric devices at the top and bottom of the optics module box	• Channel Size: **180 x 430 microns** • Sheath Flow Pressure: **18.8 kPa** Optics module temperature management hardware: **two** thermoelectric devices at the top and bottom of the optics module box
Fluorescence collection	Collection lens and light path: • Spherical mirror and aspheric Schmidt lens o **No** gel coupling, NA=1.2. o Light passes through optical fiber to **PMT area** o Light leaves the fiber and is collimated	Collection lens and light path • Spherical mirror and aspheric Schmidt lens o Gel coupled to flow cell o Light passes through optical fiber to **WDM area** o Light leaves the fiber and is collimated o Collimated light is separated by filters into desired bands

Attribute	Navios EX Flow Cytometer (K183592)	DxFLEX Flow Cytometer
	○ Collimated light is separated by filters into desired bands **PMTs** detect light and convert to electrical signals	**APDs** (Avalanche Photodiodes) detect light and convert to electrical signals
Maximum Parameter Detectors	Twelve (Forward Scatter, Side Scatter and 10 fluorescence channels)	Twelve (Forward Scatter, Side Scatter and 10 fluorescence channels)
Electronics	40 MHz sampling	25 MHz sampling
Detectors / Colors	Standard 5 PMTs (FL1 – FL5) off of 488 nm laser (blue) Standard 3 PMTs (FL6 – FL8) off of 638 nm laser (red) Standard 2 PMTs (FL9 – FL10) off of 405 nm laser (violet)	ClearLLab 10C application will require the first 10 APDs. Standard 5 APDs (FITC – PC7 off of 488 nm laser (blue) Standard 3 APDs (APC – APC-A750) off of 638 nm laser (red) Standard 2 APDs (PB450 – KO525) off of 405 nm laser (violet)
Optical Filters	Optical Filters: (SP = Short Pass, BP = Band Pass, LP = Long Pass) • FITC 550 SP - 525 BP • PE 595 SP- 575/30 BP • ECD 655 SP - 614/20 BP • PC5.5 730 SP - 695/30 BP • PC7 755 LP • APC 710 SP – 660/20 BP • APC-A700 750 SP – 725/20 BP • APC-A750 755 LP • PB 480 SP – 450/50 BP • KRO 550/40 BP	Optical Filters (all band pass): • FITC 525/40 • PE 585/42 • ECD 610/20 • PC5.5 690/50 • PC7 780/60 • APC-A750 780/60 • APC 660/10 • APC-700 712/25 • PB450 450/45 • KO525 525/40
Color Separation	Collimated beam is separated into desired components with dichroic filters.	Use filter to separate into desired components.

Attribute	Navios EX Flow Cytometer (K183592)	DxFLEX Flow Cytometer
On-board acquisition software	System Software available	SAME
Analysis Software	Kaluza C data analysis software to be used with the ClearLLab 10C application and to be used off-line. Navios EX on-board and off-line analysis software is not recommended for use of control cell and sample data analysis.	SAME, except provided analysis protocols will be specific for ClearLLab Reagents on DxFLEX Flow Cytometer CytExpert for DxFLEX software will not be recommended for use of control cell and sample data analysis.
Post-Analytical Features		
Data Reporting	Report, Plots and Statistics printouts	SAME
Cleaning Cycle Between Samples	Executed with Sheath Fluid ensuring carryover specification is met	SAME
Quality Control Techniques	• Daily Instrument Checks • Supplied Controls for ClearLLab 10C application	SAME
Cleanse Cycle	Cleaning cycle performed with FlowClean cleaning reagent as part of the daily shutdown process, before and after running samples with vital dyes that stain the tubing, and as part of troubleshooting.	SAME, except additional cleaning cycle required after running DxFLEX Daily QC Fluorospheres
Compensation		
Reagents used for compensation and sample preparation	ClearLLab Compensation Kit and Compensation Beads will be used with the ClearLLab 10C application.	SAME, except with labeling changes to include DxFLEX Flow Cytometer only
Controls and Calibrators		

Attribute	Navios EX Flow Cytometer (K183592)	DxFLEX Flow Cytometer
Assay Controls and Calibrators	Flow-Check Pro Fluorospheres Flow-Set Pro Fluorospheres	SIMILAR DxFLEX Daily QC Fluorospheres have target values assigned to monitor optical alignment and fluidics and to aid in standardization.
Process Controls	ClearLLab Control Cells (Normal and Abnormal)	SAME except with labeling changes to include DxFLEX Flow Cytometer and assay ranges specific for the DxFLEX Flow Cytometer
Instrument Software		
Processor	PowerPC	SAME
Programming Language	C++	• C# • C++
RTOS	VxWorks	N/A
Workstation Interface	Ethernet	• USB • Ethernet
Data Acquisition	Digital Pulse Processing	SAME
General	Software functionality to allow: • Patient data management – storage, review, reporting • Control data management – storage, review, reporting • System configuration management System service test and adjustment procedures.	SAME

Attribute	Navios EX Flow Cytometer (K183592)	DxFLEX Flow Cytometer
Data Processing	• Region/gates evaluation • Statistics generation Export of results to MS Excel/PDFfile	• Region/gates evaluation • Statistics generation Export of results to CSV/PDF file.
Standardization	Automatic voltage/gain adjustments	Automatic gain calibration using target value
User interface	Plots and reports	SAME
Control Software	• The acquisition software enables the user to acquire data from the Navios EX Flow Cytometer and to analyze, display, print and export acquired listmode data. The embedded software resides in the Navios EX instrument. It controls the instrument functionality including the multi-carousel loader (MCL) for sample introduction. • The embedded software controls the instruments' lasers, acquisition system and fluidics. The instrument fluidics aspirates the sample, and performs instrument maintenance functions such as startup/shutdown. The embedded software also captures and provides the data to the workstation for processing. Communication protocol	• CytExpert for DxFLEX software enables the user to acquire data from the DxFLEX flow cytometer instrument and to analyze, display, print and export acquired fcs file. • CytExpert for DxFLEX controls the instrument functionality including the multi-carousel loader (MCL) for sample introduction. • CytExpert for DxFLEX controls the instruments' lasers, acquisition system and fluidics. The instrument fluidics aspirates the sample, and performs instrument maintenance functions such as startup/shutdown. • CytExpert for DxFLEX also captures and provides the data to the workstation for processing. Communication protocol
Data Processing	• Region and Gate processing • Statistics Generation • Export to Excel Incoming data stream formatted into per-parameter vectors for improved performance of lin/log data transformations and compensation calculations	• Region and Gate processing • Statistics Generation • Export to CSV Incoming data stream formatted into per-parameter vectors for improved performance of lin/log data transformations and compensation calculations

Attribute	Navios EX Flow Cytometer (K183592)	DxFLEX Flow Cytometer
User Account Control	• Enhanced security and user permissions functionality • Multiple role assignments • User account information stored in password protected database. Additional password timeout and auto-lockout of user on repeated password failure	• Enhanced security and user permissions functionality • Multiple role assignments • User account information encrypted and stored in password protected database. • Additional password timeout and auto-lockout of user on repeated password failure. Password complexity policy.
Report generator	Panel reports & QC	SAME

Summary of Instrument Characterization and Analytical Performance Testing

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Laser Performance Characteristics	Verify stability of the laser performance of the DxFLEX Flow Cytometer over time.	None	None	Analysis of the data collected demonstrates that the DxFLEX Flow Cytometer laser performance is stable over time.
Instrument Carryover	To verify carryover of the DxFLEX Daily QC Fluorospheres in specimens on the DxFLEX Flow Cytometer after running the required daily clean	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Carryover (Section 12)	CLSI H26-A2; FDA Standards Recognition #7-210	Analysis of the data collected demonstrates that the DxFLEX Flow Cytometer meets the carryover performance requirements.
Instrument Linearity	Verify fluorescence detection is linear using standard DxFLEX Flow Cytometer settings.	None	None	Linearity of fluorescence measurements was demonstrated.

Summary of System Performance Testing:

Study	Objective	FDA Guidance Documents	Standards/ References	Testing Results
Carryover – Specimen and Reagent	To verify carryover of specimen and reagents on the DxFLEX Flow Cytometer meets performance specifications.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Carryover (Section 12)	Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard - 2nd Edition; June 2010; CLSI H26-A2; FDA Standards Recognition #7-210	Analysis of the data collected demonstrates that the DxFLEX Flow Cytometer meets carryover performance requirements.
Detection Capability	To verify that the ClearLLab 10C Reagent System on the DxFLEX Flow Cytometer meet the performance requirements for the ability to differentiate between abnormal and normal populations.	None	Wood B et al. Validation of Cell-Based Fluorescence Assays: Practice Guidelines from the ICSH and ICCS – Part V - Assay performance Criteria. Cytometry Part B (Clinical Cytometry), pp. 315-323	Analysis of the data collected demonstrates that the ClearLLab 10C Reagent System on the DxFLEX Flow Cytometer meet the performance requirements for Detection Capability.
Precision – Control Material	Demonstrate system imprecision using control material as a surrogate for a stabilized sample	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Precision (Section 9)	CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. FDA Standards Recognition #7-251	Analysis of the data collected demonstrates that the ClearLLab 10C Reagent System on the DxFLEX Flow Cytometer meets performance requirements for repeatability and reproducibility.
Precision – Multi-Site with Clinical Specimens	Demonstrate assay repeatability and reproducibility using both normal and clinical specimens.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Precision (Section 9)	CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. FDA Standards Recognition #7-251 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Second	Analysis of the data collected demonstrates that the ClearLLab 10C Reagent System on the DxFLEX Flow Cytometer meets performance requirements for repeatability and reproducibility.

Study	Objective	FDA Guidance Documents	Standards/ References	Testing Results
			Edition; CLSI EP12-A2; FDA Standards Recognition #7-152	
Precision – Operator and Instrument Variability	Demonstrate system imprecision performance of the ClearLLab 10C Reagent System on the DxFLEX Flow Cytometer using the same specimen prepared by three (3) operators, twice a day, on two (2) DxFLEX Flow Cytometers.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Precision (Section 9)	CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. FDA Standards Recognition #7-251 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Second Edition; CLSI EP12-A2; FDA Standards Recognition #7-152	The ClearLLab 10C Reagent System, when run on each specimen type by different operators on different DxFLEX Flow Cytometers, demonstrated acceptable precision performance and met acceptance criteria.
Clinical Accuracy	Demonstrate the performance equivalency between ClearLLab 10C Reagent System on DxFLEX cytometers (Test Method) and Navios EX flow cytometers (Predicate Method) by a multi-site evaluation of the qualitative immunophenotype agreement between the two systems using specimens from donors in the intended use population.	None	CLSI H43-A2: Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells – Second Edition; FDA Standards Recognition #7-150 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Second Edition; CLSI EP12-Ed3; FDA Standards Recognition #7-315 CLSI EP09-A3: Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline-3rd Edition; FDA Standards Recognition #7-296	Analysis of the data collected demonstrates that the ClearLLab 10C panels are able identify the abnormal population when compared to the predicate.

Summary of Accessory Reagents Performance Testing:

Study	Objective	FDA Guidance Documents	Standards/ References	Testing Results
DxFLEX Daily QC Fluorospheres Analyte Value Assignment	Define DxFLEX Daily QC Fluorospheres Target Value ranges for use with the ClearLLab 10C Reagent System and define a process for ranges transfer from one lot of DxFLEX Daily QC Fluorospheres.	None	None	Analysis of the data collected demonstrates that appropriate DxFLEX Daily QC Fluorospheres Target Value ranges are defined for use with the ClearLLab 10C Reagent System and that a process for range transfer from one lot of DxFLEX Daily QC Fluorospheres to another one is in place.

Substantial Equivalence Conclusion to Demonstrate Safety, Effectiveness & Equivalent Performance to Predicate:

The ClearLLab 10C Reagents on the DxFLEX Flow Cytometer, that is the subject of this submission, in concert with the conclusions drawn from the performance testing discussed above demonstrate that when compared to the predicate device is as safe, as effective, and meets the performance acceptance criteria.

In summary, the ClearLLab 10C Reagents on the DxFLEX Flow Cytometer as described in this submission is substantially equivalent in terms of safety and effectiveness to its predicate devices.

The ClearLLab 10C Reagents on the DxFLEX Flow Cytometer is substantially equivalent to the ClearLLab 10C Reagents on the Navios EX Flow Cytometer.

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.