DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 23, 2017

Beckman Coulter
Zaily Rodriguez
Staff Regulatory Affairs Specialist
11800 Sw 147th Ave
Miami, Florida 33196-2500

Re: K162897
Trade/Device Name: Navios EX Flow Cytometer, 6 Color/2 Laser, Navios EX Flow Cytometer, 8 Color/2 Laser, Navios EX Flow Cytometer, 10 Color/3 Laser
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: OYE, PDX
Dated: May 24, 2017
Received: May 25, 2017

Dear Zaily Rodriguez:

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. 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); 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 and Part 809), please contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

Kelly Oliner -S

For
Leonthena R. Carrington, M.S., MBA, MT
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162897

Device Name
Navios EX Flow Cytometer

Indications for Use *(Describe)*

The Navios EX Flow Cytometer is intended for use as an in vitro diagnostic device for immunophenotyping using up to four fluorescent detection channels using a blue (488 nm) laser 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.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162897

Device Name
CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents

Indications for Use *(Describe)*
CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents are for use on the COULTER EPICS XL/XL-MCL, Cytomics FC 500, Navios and Navios EX Flow Cytometers. The reagents are also used with the tetraONE System for COULTER EPICS XL/XL-MCL Flow Cytometer, the tetraCXP System for FC 500 Flow Cytometry System, Navios tetra Software for the Navios System, and Navios EX tetra Software for the Navios EX System.

Used alone or in combination with the automated systems, the reagents are intended "For In Vitro Diagnostic Use" and allow simultaneous identification and enumeration of total CD3+, total CD4+, total CD8+, dual CD3+CD4+, dual CD3+CD8+ and/or total CD3+, CD19+ and CD3-CD56+ lymphocyte percentages and absolute counts in whole blood by flow cytometry. The systems also provide the CD4/CD8 ratio when using CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5. These reagents are indicated for use in the immunologic assessment of patients having or suspected of having immune deficiency.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Flow-Set Pro Fluorospheres

Indications for Use *(Describe)*
Flow-Set Pro Fluorospheres is a suspension of fluorescent microspheres used as an aid in standardizing forward scatter, side scatter, and fluorescence detectors (FL1-4) on the Cytomics FC 500, Navios and Navios EX Flow Cytometers.

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)

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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Flow-Count Fluorospheres

Indications for Use *(Describe)*
Flow-Count Fluorospheres is a fluorescent microsphere reagent for direct determination of lymphocytes and lymphocyte subsets cell population percentages and absolute counts in biological specimens using EPICS XL/XL-MCL, Cytomics FC500, Navios and Navios EX flow cytometry systems as well as CD34+ cell population percentages and absolute counts in biological specimens using EPICS XL/XL-MCL and Cytomics FC500 flow cytometry systems.

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)

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510(k) Summary for
Navios EX Flow Cytometry System

510(k) Owner / Submitter Information

Name: Beckman Coulter Inc.
Address: 11800 SW 147th Ave., Miami, FL 33196
Phone #: (305) 380-4191
Contact Person: Nancy Nadler
Email Address: nancy.nadler@beckman.com
Date Submitted: 24 May 2017

Device Information

Trade Name: Navios EX Flow Cytometer
Classification: Class II
Classification Name: Automated Differential Cell Counter (21 CFR 864.5220)
Product Code: OYE
Panel: Hematology
Original 510(k) Clearance / Predicate: K130373, SE date: September 18, 2013

Trade Name: Navios EX tetra Software
Classification: Class II
Classification Name: Automated Differential Cell Counter (21 CFR 864.5220)
Product Code: OYE
Panel: Hematology
Original 510(k) Clearance / Predicate: K130373, SE date: September 18, 2013

Predicate Device Information

Predicate Product	510(k) Number	Date Cleared	Classification	21 CFR	Product Code
Navios Flow Cytometer	K130373	9/18/13	Class II	864.5220	OYE
Navios tetra Software	K130373	9/18/13	Class II	864.5220	OYE

Device Description

The Navios EX Flow Cytometry System consists of:

- Navios EX Flow Cytometer
- Navios EX tetra Software
- Navios EX Software off-line analysis tool
- CYTO-STAT tetraCHROME reagents

- Flow-Set Pro Fluorospheres
- Flow-Check Pro Fluorospheres
- Flow-Count Fluorospheres
- Immuno-Trol Cells
- Immuno-Trol Low Cells
- COULTER IMMUNOPREP Reagent System
- QuickCOMP 2 and QuickCOMP 4 Kits
- CYTO-COMP Cell Kit
- ISOFLOW Sheath Fluid
- FlowClean Cleaning Reagent
- TQ-Prep Workstation *(accessory for sample preparation)*
- PrepPlus 2 Workstation *(accessory for sample preparation)*

The Navios EX Flow Cytometry System is the next generation product in the Navios Flow Cytometry family. With the Navios EX flow cytometer and associated software, the following modifications have been introduced:

Technological Characteristics Comparison to Predicate (Refer to Tables 1 and 2)

- Replacement of optical assemblies and flow cell
- Replacement of the existing 488nm laser with a comparable 488nm laser
- Replacement of the band-pass filter (FL3) used for ECD dye
- Replacement of the Forward Scatter mask with a new mask configuration
- Replacement of the existing fixed aspiration probe with an adjustable one. This probe is adjusted by the service engineer only to account for the sample tube employed at the customer's laboratory.
- Change to the optics module temperature management hardware
- Minor change to the sheath pressure
- Minor changes to the Navios EX tetra algorithm

Table 1: Similarities between Navios and Navios EX Flow Cytometers

Attribute	Navios Flow Cytometer (Predicate) K130373	New Navios EX Flow Cytometer (Subject Device)
Intended Use	The Navios Flow Cytometer is intended for use as an in vitro diagnostic device for immunophenotyping. It can be used in conjunction with the following monoclonal antibody reagents and software package: • CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 monoclonal antibody reagents. These reagents provide identification and enumeration of CD3+CD4+, CD3+CD8+, CD3+, CD19+ and CD3-CD56+ lymphocyte percentages and absolute counts in peripheral whole blood. Absolute counts may be determined by the Navios flow cytometer using Flow-Count Fluorospheres (single platform technology method) or separate hematology results (dual platform method). These reagents are indicated for use in the immunologic assessment of patients having or suspected of having immune deficiency. • Navios tetra Software for automated analysis and results with CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 monoclonal antibody reagents. Navios Software may be installed on an independent computer workstation for off-line analysis of listmode files generated by the Navios Flow Cytometer with the monoclonal antibody reagents and software package listed above. The off-line analysis must be performed in accordance with the product labeling.	*Similar – Differences are underlined:* The Navios EX Flow Cytometer is intended for use as an in vitro diagnostic device for immunophenotyping using up to four fluorescent detection channels with a blue (488 nm) laser 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.
Device Classification	864.5220, Automated Differential Cell Counter	Same

Attribute	Navios Flow Cytometer (Predicate) K130373	New Navios EX Flow Cytometer (Subject Device)
Product Code	OYE	Same
Manufacturer	Beckman Coulter, Inc.	Same
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 listmode 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		
System Configuration	• Bench top • Printer • PC based workstation running Microsoft Windows Vista or WIN7 application specific software	Same except PC based workstation runs WIN7 only
tetraCHROME Reagent Assay	• Two tube monoclonal antibody reagent assay o CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 o CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 • Provides identification and enumeration of Total CD3+, CD3+CD4+, CD3+CD8+, CD3-CD56+, and CD19+ percentages and absolute count results	Same
tetraCHROME Reagents specimen and prepared sample stability claims	• Specimen stability – 24 hours room temperature • Prepared sample stability o 2 hours room temperature o 24 hours refrigerated temperature	Same
Sample Preparation with Monoclonal Antibodies	Off-board sample preparation following instructions provided with cleared monoclonal antibody reagent	Same

Attribute	Navios Flow Cytometer (Predicate) K130373	New Navios EX Flow Cytometer (Subject Device)
Sample Presentation	Prepared sample added to a daughter 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 via tube access door	Same
Aspiration Pathway	Same aspiration pathway used for automated and manual presentation	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
Analytical Features		
Maximum Parameter Detectors	Six (FS, SS, FL1 – FL4)	Same
Electronics	40 MHz sampling Digital integrator circuitry w/ early stage ADC	Same
Photomultipler Tubes (PMTs) / Colors	Standard 4 PMTs (FL1 - FL4) off of 488 nm laser	Same
Color Separation	Collimated beam is separated into desired components with dichroic filters.	Same
On-board analysis software	System Software available	Same with minor modifications made to accommodate the new laser
Off-line analysis software	Off-line Software package available	Same with minor modifications made to accommodate the new laser
Analysis Algorithm	Tetra analysis software available	Same with minor modifications implemented to address differences in select data patterns seen on the Navios EX
Post-Analytical Features		
Data Reporting	FlowPAGE, Panel Report, Plots and Statistics printouts	Same

Attribute	Navios Flow Cytometer (Predicate) K130373	New Navios EX Flow Cytometer (Subject Device)
Cleaning Cycle Between Samples	Executed with IsoFlow Sheath Fluid ensuring carryover specification is met	Same
Quality Control Techniques	• Daily Instrument Checks • Commercial Controls • Inter-laboratory Quality Assurance Program (IQAP)	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
Compensation and Sample Preparation Reagents		
Reagents used for compensation and sample preparation	CYTO-COMP Cell Kit IMMUNOPREP Reagent System QuickCOMP2 and 4 Kits CytoTrol Cells	Same with the exception of not using CytoTrol
Controls and Calibrators		
Assay Controls and Calibrators	Flow-Check Pro Fluorospheres Flow-Count Fluorospheres Flow-Set Pro Fluorospheres IMMUNO-TROL Cells IMMUNO-TROL Low Cells	Same

Table 2: Differences between Navios and Navios EX Flow Cytometers

Attribute	Navios Flow Cytometer (Predicate) K130373	New Navios EX Flow Cytometer (Subject Device)
Pre-Analytic Features		
Sample Aspiration Probe	Fixed height	Adjustable (by Beckman Coulter field service personnel)
Analytical Features		
Lasers / Driver Boards	IVD configuration – 488 nm • Diode Pumped Solid State (DPSS), 22mW • 3 laser driver boards (488 nm, 638 nm, 405 nm)	IVD configuration – 488 nm: Same with the exception of: • Laser Diode, 55mW • Single custom 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	Same with the exception of the band-pass filter and forward scatter mask redesign
Optics	Achromatic Crossed Cylinder Lens	Spherical 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: two thermoelectric devices at the top and bottom of the optics module box	New Flow Cell with modified channel size and sheath flow pressure. No gel coupling of the lens and optics module temperature management hardware modified.
Fluorescence collection	Collection lens and light path • 1st and 2nd lens set: o Gel coupled to flow cell, numerical aperture (NA)=1.2 o Light passes through optical fiber to PMT area o Light leaves the fiber and is collimated o Collimated light is separated by filters into desired bands PMTs detect light and convert to electrical signals	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 o Collimated light is separated by filters into desired bands PMTs detect light and convert to electrical signals
Optical Filters	Optical Filters: (SP = Short Pass, BP = Band Pass) • FL1 FITC 550 SP - 525 BP • FL2 PE 595 SP - 575/30 BP • FL3 ECD 655 SP - 620/30 BP	All filters same with the exception of: FL3 ECD is 655 SP - 614/20 BP

Attribute	Navios Flow Cytometer (Predicate) K130373	New Navios EX Flow Cytometer (Subject Device)
	• FL4 PC5 730 SP - 695/30 BP	
Side Angle Light Scatter	• Separate lens system focuses the light onto an optical fiber • Light exiting the optical fiber is focused onto a diode through a filter to pass 488nm only	• Side Scatter light is collected from the same side of the flow cell and focused onto the optical fiber by the spherical mirror. • The side scatter is split off from the fluorescence signal by a dichroic mirror before entering the filter/PMT assembly.
Gating Strategy	The main Lymphocyte population is determined through a gate including the LADJ and GADJ regions.	Minor changes to the algorithm to accommodate data pattern changes resulting from the new optics module.

Intended Use:

Navios EX Flow Cytometry System Indications for Use:

The Navios EX Flow Cytometer is intended for use as an in vitro diagnostic device for immunophenotyping using up to four fluorescent detection channels using a blue (488 nm) laser 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.

Navios EX tetra Software Indications for Use:

The Navios EX tetra Software is intended for use as an in vitro diagnostic device for immunophenotyping with CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/ CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 monoclonal antibody reagents on the Navios EX Flow Cytometer.

It provides automated analysis and results for the identification and enumeration of CD3+CD4+, CD3+CD8+, CD3+, CD19+ and CD3-CD56+ lymphocyte percentages and absolute counts in peripheral whole blood. Absolute counts may be determined by the Navios EX Flow Cytometers using Flow-Count Fluorospheres (Single Platform Technology (SPT) Method) or separate hematology results (Dual Platform Method). It is indicated for use in the immunologic assessment of patients having or suspected of having immune deficiency.

Summary of Navios EX Flow Cytometer Performance Testing

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Laser Performance Characteristics	Verify stability of the laser performance of the Navios EX flow cytometer over time.	None	None	Analysis of the data collected demonstrates that the Navios EX laser performance is stable over time.
Instrument Carryover	To verify carryover using Flow-Check Pro fluorospheres meets performance specifications.	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 Navios EX meets the carryover performance requirements.
Instrument Linearity	Verify fluorescence detection is linear using standard Navios EX settings.	None	None	Linearity of fluorescence measurements was demonstrated.
Assay Carryover	To verify carryover of whole blood and reagents on the Navios EX 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 Navios EX meets carryover performance requirements.

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Assay Linearity	Verify the linear range of the absolute values for each lymphocyte subset populations on the Navios EX Flow Cytometry System.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Linearity (Section 11)	Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline; April 2003. CLSI EP06-A; FDA Standards Recognition #7-193	Analysis of the data collected demonstrates that the Navios EX meets the linearity performance requirements.
Detection Capability	To verify that the Navios EX meets the performance requirements for Limit of Blank (LoB), Limit of Detection (LoD), Limit of Quantitation (LLoQ).	None	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition; CLSI EP17-A2; FDA Standards Recognition #7-233	Analysis of the data collected demonstrates that the Navios EX meets the performance requirements for LOB, LOD, and LOQ in whole blood.
Specimen and Prepared Sample Stability	Stability of whole blood samples will be evaluated to verify specimen and prepared sample stability claims.	None	None	Analysis of the data collected demonstrates that the Navios EX Flow Cytometry System meets the requirements for specimen and prepared sample stability.

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Analytical Measuring Interval	Establish the Navios EX Analytical Measuring Interval (AMI) based on the system's capability (Linearity, Limit of Quantitation (LOQ)), consideration of the predicate and the application's intended use population.	None	None	AMI of the Navios EX was verified to meet the acceptance criteria.
Comparability of Navios EX Models (6C/2L, 8C/2L, 10C/3L)	Verify comparability of performance of each Navios EX configuration to the predicate Navios.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Accuracy (Section 8)	Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard – 2nd Edition; June 2010; CLSI H26-A2; FDA Standards Recognition # 7-210 CLSI EP09-A3, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline--Second Edition (Interim Revision)	Analysis of the data collected demonstrates that the Navios EX Flow Cytometry System meets the performance requirements when compared to the predicate device.

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Precision – Across Model Configurations	Demonstrate system imprecision using control material as a surrogate for a stabilized sample on each of the three Navios EX configurations.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Precision (Section 9)	CLSI EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.	Analysis of the data collected demonstrates that the Navios EX meets performance requirements.
Method Comparison	To evaluate bias between the subject device versus the predicate.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Accuracy (Section 8)	Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard – 2nd Edition; June 2010; CLSI H26-A2; FDA Standards Recognition # 7-210 CLSI EP09-A3, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline--Second Edition (Interim Revision)	Analysis of the data collected demonstrates that the Navios EX Flow Cytometry System meets the performance requirements when compared to the predicate device.

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Precision – Long Term Imprecision	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-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.	Analysis of the data collected demonstrates that the Navios EX meets performance requirements for Long Term Imprecision.
Precision – Whole Blood Repeatability	Evaluate sample imprecision using a precision profile approach to estimate repeatability at various medical decision levels and data percentiles.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Precision (Section 9)	CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers CLSI EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.	Analysis of the data collected demonstrates that the Navios EX meets performance requirements for Whole Blood Repeatability.
Precision – Whole Blood Repeatability – Site To Site Variability	Evaluate site-to-site variability performance of CYTO-STAT tetraCHROME reagents for CD3+CD4+ percentage and absolute counts using whole blood specimens	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Precision (Section 9)	None	Site-to-site variability for CD3+CD4+ percentages and absolute counts were found to be acceptable

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Adult Reference Interval	Establish adult reference intervals for lymphocyte subset analysis on the Navios EX Flow Cytometry System.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells – Reference Values (Section 14)	EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition.	Adult reference intervals were established and confirmed to be consistent with published values for T, B, and NK lymphocyte subsets.

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

The Navios EX Flow Cytometry System, 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 Navios EX Flow Cytometry System as described in this submission is substantially equivalent in terms of safety and effectiveness to its predicate devices.

- The Navios EX Flow Cytometer, Navios EX tetra software, and tetraCHROME reagents are substantially equivalent to the Navios Flow Cytometer, Navios tetra software, and tetraCHROME reagents.

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.