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

January 27, 2016

Beckman Coulter, Inc.
c/o Mr. Anthony Dennis
Staff Regulatory Affairs Specialist
11800 SW 147th Avenue, M/S 31-B06
Miami, FL 33196-2500

Re: K141932
Trade/Device Name: AQUIOS CL Flow Cytometry System
AQUIOS Tetra-1 and Tetra-2+ Monoclonal Antibody Reagents
AQUIOS Lysing Reagent Kit
AQUIOS Immuno-Trol and Immuno-Trol Low Cells
Regulation Number: 21 CFR §864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: OYE, JPK, GGK
Dated: March 5, 2015
Received: March 9, 2015

Dear Mr. Dennis:

This letter corrects our substantially equivalent letter of April 10, 2015.

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 Parts 801 and 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 Parts 801 and 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″ (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 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 yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
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)*
k141932

Device Name
AQUIOS CL Flow Cytometry System

Indications for Use *(Describe)*
The AQUIOS CL Flow Cytometer is intended for use with in vitro diagnostic flow cytometric applications using up to four fluorescent detection channels using a blue (488 nm) laser, two light scatter detection channels and electronic volume (EV). It is used in conjunction with the following reagents and software package.

AQUIOS Tetra-1 Panel and AQUIOS Tetra-2+ Panel monoclonal antibody reagents are for use on the AQUIOS CL Flow Cytometer with peripheral whole blood for immunophenotyping. These reagents are indicated for use in the immunologic assessment of patients having, or suspected of having, immune deficiency. These reagents provide identification and enumeration of;
- AQUIOS Tetra-1 Panel Monoclonal Antibody Reagent
• Total CD3+, CD3+CD4+,CD3+CD8+, CD3+CD4+/CD3+CD8+ (ratio only) lymphocyte percentages and absolute counts.
• CD45+ absolute count
• CD45+ Low SS (lymphocytes) percentage and absolute count
AQUIOS Tetra-2+ Panel Monoclonal Antibody Reagent
• Total CD3+, CD3-CD19+, CD3-CD56+ and/or CD16+ lymphocyte percentages and absolute counts.
• CD45+ absolute count
• CD45+ Low SS (lymphocytes) percentage and absolute count

AQUIOS Flow Cytometry Software may be run on an independent computer workstation for off-line analysis of results generated by the AQUIOS CL Flow Cytometer with the monoclonal antibody reagents listed above. The off-line analysis must be performed in accordance with the product labeling.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
k141932

Device Name
AQUIOS Tetra-1 and Tetra-2+ Monoclonal Antibody Reagents

Indications for Use *(Describe)*
AQUIOS Tetra-1 Panel and AQUIOS Tetra-2+ Panel monoclonal antibody reagents are for use on the AQUIOS CL Flow Cytometer with peripheral whole blood for immunophenotyping. These reagents are indicated for use in the immunologic assessment of patients having, or suspected of having, immune deficiency. These reagents provide identification and enumeration of;

- AQUIOS Tetra-1 Panel Monoclonal Antibody Reagent
• Total CD3+, CD3+CD4+,CD3+CD8+, CD3+CD4+/CD3+CD8+ (ratio only) lymphocyte percentages and absolute counts.
• CD45+ absolute count
• CD45+ Low SS (lymphocytes) percentage and absolute count
- AQUIOS Tetra-2+ Panel Monoclonal Antibody Reagent
• Total CD3+, CD3-CD19+, CD3-CD56+ and/or CD16+ lymphocyte percentages and absolute counts.
• CD45+ absolute count
• CD45+ Low SS (lymphocytes) percentage and absolute count

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) Number *(if known)*
k141932

Device Name
AQUIOS Lysing Reagent Kit

Indications for Use *(Describe)*

AQUIOS Lysing Reagent Kit is used as part of the AQUIOS flow cytometer system. The kit consists of two reagents used by AQUIOS flow cytometers to prepare whole blood samples for analysis of white blood cells.
Type of

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)*
k141932

Device Name
AQUIOS Immuno-Trol and Immuno-Trol Low Cells

Indications for Use *(Describe)*

AQUIOS IMMUNO-TROL Cells are assayed, lysable whole blood quality control product for immunophenotyping analysis using monoclonal antibody reagents and flow cytometry. It provides a positive cell control that is processed in the same manner as a whole blood sample. This allows verification of instrument and reagent performance. It also verifies the methods used for staining targeted cells, lysing erythrocytes, and analyzing samples by the AQUIOS CL Flow Cytometer.

AQUIOS IMMUNO-TROL Low Cells are assayed, lysable whole blood quality control product for immunophenotyping analysis using monoclonal antibody reagents and flow cytometry. It provides a positive cell control that is processed in the same manner as a whole blood sample. This allows verification of instrument and reagent performance. It also verifies the methods used for staining targeted cells, lysing erythrocytes, and analyzing samples by the AQUIOS CL Flow Cytometer.

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
AQUIOS CL Flow Cytometry System

510(k) Owner / Submitter Information

Name: Beckman Coulter Inc.
Address: 11800 SW 147th Ave., Miami, FL 33196
Phone #: (305) 380-4509
Fax #: (305) 380-4344
Contact Person: Anthony Dennis
Email Address: adennis@beckman.com
Date Updated: April 9, 2015

Device Information

Trade Name: **AQUIOS CL Flow Cytometry System**
Common Name: AQUIOS CL
Classification Name: Automated differential cell counter (21 CFR 864.5220)
Classification: Class II
Product Code: OYE
Panel: Hematology

Trade Name: **AQUIOS Tetra-1 and Tetra-2+ Monoclonal Antibody Reagents**
Common Name: AQUIOS Tetra-1 Panel CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and AQUIOS Tetra-2+ Panel CD45-FITC/(CD56+CD16)-RD1/CD19-ECD/CD3-PC5
Classification Name: Automated differential cell counter (21 CFR 864.5220)
Classification: Class II
Product Code: OYE
Panel: Hematology

Trade Name: **AQUIOS Lysing Reagent Kit**
Common Name: AQUIOS Lysing Reagent Kit
Classification Name: Red cell lysing reagent (21 CFR 864.8540), Automated differential cell counter (21 CFR 864.5220)
Classification: Class I Non-Exempt [due to limitations of the exemptions of 21 CFR 864.9(c)(1) and (c)(3)]
Product Code: GGK, OYE [as used as part of the AQUIOS flow cytometry system]
Panel: Hematology

Trade Name: **AQUIOS Immuno-Trol and Immuno-Trol Low Cells**
Common Name: AQUIOS Immuno-Trol and Immuno-Trol Low
Classification Name: Hematology quality control mixture (21 CFR 864.8625)
Classification: Class II
Product Code: JPK
Panel: Hematology

Predicate Device Information

Predicate Product	510(k) Number	Date Cleared	Classification	21 CFR	Product Code
CaliBRITE 3 Color and FACSComp	K961623	6/07/96	Class II	864.5220	GKZ
CaliBRITE APC beads CaliBRITE 4 kit (unlabeled, FITC-, PE-, PerCP- and APC- labeled CaliBRITE beads), and FACSComp software (FACSCalibur)	K973483	2/17/98	Class II	864.5220	GKZ
MultiTEST CD3/CD8/CD45/CD4	K974360	03/11/98	Class II	864.5220	GKZ
Multitest CD3/CD16+56/CD45/CD19 Reagent and Multitest IMK Kit Lysing Solution with BD TruCount Tubes	K980858	5/22/98	Class II	864.5220	GKZ
Unicel DxH 800	K140911	09/05/14	Class II	864.5220	GKZ
Immuno-Trol Control Cells	K984216	03/16/99	Class II	864.8625	JPK
Immuno-Trol Low Cells	K013842	12/13/01	Class II	864.8625	JPK

Device Description

The AQUIOS CL Flow Cytometry System is composed of the following components:

- AQUIOS CL Flow Cytometer
- AQUIOS System Software
- AQUIOS Tetra-1 Panel CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5
- AQUIOS Tetra-2+ Panel CD45-FITC/(CD56+CD16)-RD1/CD19-ECD/CD3-PC5
- AQUIOS Immuno-Trol Cells
- AQUIOS Immuno-Trol Low Cells
- AQUIOS Lysing Reagent Kit

The AQUIOS CL Flow Cytometer uses flow cytometric principles to determine qualitative and quantitative measurements of biological and physical properties of cells

and other particles. These properties are measured when the cells pass through the laser beam(s) in single file.

The AQUIOS System Software is designed for the AQUIOS CL flow cytometer. It includes the algorithms and test definitions that provide automated analysis and results for AQUIOS Tetra-1 and 2+ reagents; this application cannot be modified by the user.

The AQUIOS Flow Cytometry System also offers an optional standalone offline workstation. This workstation is identical to the workstation that is physically connected to the instrument and can be used for off-line analysis of results generated by the AQUIOS CL Flow Cytometer with AQUIOS Tetra-1 and Tetra-2+ reagents and AQUIOS System software according to the product labeling.

AQUIOS Tetra-1 Panel CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 reagent provides identification and enumeration of CD45+, CD45+ Low SS, and CD3+/CD4+, CD3+/CD8+, and CD3+ lymphocyte percentages and absolute counts in peripheral whole blood. AQUIOS Tetra-2+ Panel CD45-FITC/(CD56+CD16)-RD1/CD19-ECD/CD3-PC5 provides identification and enumeration of CD45+, CD45+ Low SS, and CD3+, CD3-/CD19+ and CD3-/CD56+CD16+ lymphocyte percentages and absolute counts in peripheral whole blood. Additionally, both panels provide for CD45+ absolute count and CD45+ Low SS absolute count and percentage.

AQUIOS Immuno-Trol and Immuno-Trol Low Cells are assayed, lysable whole blood quality control product for immunophenotyping analysis using monoclonal antibody reagents and flow cytometry. It provides a positive cell control that is processed in the same manner as a whole blood sample. This allows verification of instrument and reagent performance. It also verifies the methods used for staining targeted cells, lysing erythrocytes, and analyzing samples by the AQUIOS CL Flow Cytometer.

The AQUIOS CL Flow Cytometer uses on-board sample preparation as part of the overall system workflow. The AQUIOS Lysing Reagent Kit is comprised of two ready-to-use reagents: Reagent A lyses the red blood cells, Reagent B quenches the solution, slowing the lyse reaction down in preparation for analysis. This reagent system provides a rapid, no-wash, standardized, whole blood lysing solution for sample to sample, and laboratory to laboratory reproducibility.

Intended Use:

AQUIOS CL Flow Cytometry System Indications for Use:

The AQUIOS CL Flow Cytometer is intended for use with in vitro diagnostic flow cytometric applications using up to four fluorescent detection channels using a blue (488 nm) laser, two light scatter detection channels and electronic volume (EV). It is used in conjunction with the following reagents and software package.

AQUIOS Tetra-1 Panel and AQUIOS Tetra-2+ Panel monoclonal antibody reagents are for use on the AQUIOS CL Flow Cytometer with peripheral whole blood for immunophenotyping. These reagents are indicated for use in the immunologic assessment of patients having, or suspected of having, immune deficiency. These reagents provide identification and enumeration of;

- AQUIOS Tetra-1 Panel Monoclonal Antibody Reagent
  - Total CD3+, CD3+CD4+,CD3+CD8+, CD3+CD4+/CD3+CD8+ (ratio only) lymphocyte percentages and absolute counts.
  - CD45+ absolute count
  - CD45+ Low SS (lymphocytes) percentage and absolute count
- AQUIOS Tetra-2+ Panel Monoclonal Antibody Reagent
  - Total CD3+, CD3-CD19+, CD3-CD56+ and/or CD16+ lymphocyte percentages and absolute counts.
  - CD45+ absolute count
  - CD45+ Low SS (lymphocytes) percentage and absolute count

AQUIOS Flow Cytometry Software may be run on an independent computer workstation for off-line analysis of results generated by the AQUIOS CL Flow Cytometer with the monoclonal antibody reagents listed above. The off-line analysis must be performed in accordance with the product labeling.

AQUIOS Tetra-1 and Tetra-2 Indications for Use:

AQUIOS Tetra-1 Panel and AQUIOS Tetra-2+ Panel monoclonal antibody reagents are for use on the AQUIOS CL Flow Cytometer with peripheral whole blood for immunophenotyping. These reagents are indicated for use in the immunologic assessment of patients having, or suspected of having, immune deficiency. These reagents provide identification and enumeration of;

- AQUIOS Tetra-1 Panel Monoclonal Antibody Reagent
  - Total CD3+, CD3+CD4+,CD3+CD8+, CD3+CD4+/CD3+CD8+ (ratio only) lymphocyte percentages and absolute counts.
  - CD45+ absolute count
  - CD45+ Low SS (lymphocytes) percentage and absolute count
- AQUIOS Tetra-2+ Panel Monoclonal Antibody Reagent
  - Total CD3+, CD3-CD19+, CD3-CD56+ and/or CD16+ lymphocyte percentages and absolute counts.
  - CD45+ absolute count
  - CD45+ Low SS (lymphocytes) percentage and absolute count

AQUIOS Immuno-Trol and Immuno-Trol Low Cells Indications for Use:

AQUIOS IMMUNO-TROL Cells are assayed, lysable whole blood quality control product for immunophenotyping analysis using monoclonal antibody reagents and flow cytometry. It provides a positive cell control that is processed in the same manner as a whole blood sample. This allows verification of instrument and reagent performance. It also verifies the methods used for staining targeted cells, lysing erythrocytes, and analyzing samples by the AQUIOS CL Flow Cytometer.

AQUIOS IMMUNO-TROL Low Cells are assayed, lysable whole blood quality control product for immunophenotyping analysis using monoclonal antibody reagents and flow cytometry. It provides a positive cell control that is processed in the same manner as a whole blood sample. This allows verification of instrument and reagent performance. It also verifies the methods used for staining targeted cells, lysing erythrocytes, and analyzing samples by the AQUIOS CL Flow Cytometer.

AQUIOS Lysing Reagent Kit:

AQUIOS Lysing Reagent Kit is used as part of the AQUIOS flow cytometer system. The kit consists of two reagents used by AQUIOS flow cytometers to prepare whole blood samples for analysis of white blood cells.

Technological Characteristics Comparisons to Predicate

AQUIOS CL Flow Cytometer Device Comparison Tables:

Similarities			
	Predicate FACSCalibur		Device
Characteristic	**CaliBRITE APC beads CaliBRITE 4 kit (unlabeled, FITC-, PE-, PerCP- and APC- labeled CaliBRITE beads), and FACSComp software**	**CaliBRITE 3 Color and FACSComp**	**AQUIOS CL Flow Cytometer**
Intended Use*	For flow cytometer set up and monitoring of instrument performance prior to performing reticulocyte enumeration or immunophenotyping applications. Flow cytometry has been found useful in monitoring some forms of immune disease. * Only similar parameters of both devices are presented here. Refer to DxH 800 SE table for other parameters.	For flow cytometer set up and monitoring of instrument performance.	The AQUIOS CL Flow Cytometer is intended for use with in vitro diagnostic flow cytometric applications using up to four fluorescent detection channels using a blue (488 nm) laser, two light scatter detection channels and electronic volume (EV). It is used in conjunction with the following reagents and software package. AQUIOS Tetra-1 Panel and AQUIOS Tetra-2+ Panel monoclonal antibody reagents are for use on the AQUIOS CL Flow Cytometer with peripheral whole blood for immunophenotyping. These reagents are indicated for use in the immunologic assessment of patients having, or suspected of having, immune deficiency. These reagents provide

Similarities			
	Predicate FACSCalibur		Device
Characteristic	**CaliBRITE APC beads CaliBRITE 4 kit (unlabeled, FITC-, PE-, PerCP- and APC- labeled CaliBRITE beads), and FACSComp software**	**CaliBRITE 3 Color and FACSComp**	**AQUIOS CL Flow Cytometer**
			identification and enumeration of; - AQUIOS Tetra-1 Panel Monoclonal Antibody Reagent • Total CD3+, CD3+CD4+,CD3+CD8+, CD3+CD4+/CD3+CD8+ (ratio only) lymphocyte percentages and absolute counts. - AQUIOS Tetra-2+ Panel Monoclonal Antibody Reagent • Total CD3+, CD3-CD19+, CD3-CD56+ and/or CD16+ lymphocyte percentages and absolute counts. AQUIOS Flow Cytometry Software may be run on an independent computer workstation for off-line analysis of results generated by the AQUIOS CL Flow Cytometer with the monoclonal antibody reagents listed above. The off-

Similarities			
	Predicate FACSCalibur		**Device**
Characteristic	**CaliBRITE APC beads CaliBRITE 4 kit (unlabeled, FITC-, PE-, PerCP- and APC- labeled CaliBRITE beads), and FACSComp software**	**CaliBRITE 3 Color and FACSComp**	**AQUIOS CL Flow Cytometer**
			line analysis must be performed in accordance with the product labeling.
Device Classification	Class II 864.5220		Same
Sample Analysis	• Principle of analysis – Flow cytometric • Detection hardware – Lasers, fluidics, optics, electronics • Sample analysis pathway		Same
Optics	Laser light delivered by mirrors, prisms, and lenses Emitted light delivered by mirrors		Same
Workstation	Software functionality to allow – • Patient data management – storage, review, reporting to LIS • Control data management – storage, review, reporting • System configuration management • System service test and adjustment procedures		Same

Differences			
	Predicate FACSCalibur		**Device**
Characteristic	**CaliBRITE APC beads CaliBRITE 4 kit (unlabeled, FITC-, PE-, PerCP- and APC-labeled CaliBRITE beads), and FACSComp software**	**CaliBRITE 3 Color and FACSComp**	**AQUIOS CL Flow Cytometer**
Product Code	GKZ		OYE
System Configuration	BD FACSCalibur with FACS Loader Option and BD FACStation™ Mac Pro computer and Cell Quest SW		AQUIOS System with Reagent Cart and All-in-One Touch Screen Computer loaded with AQUIOS System Software, Database, and Tetra Tests (Tetra 1, Tetra 2, and Tetra Combo)
Operating System	MAC OS 9		Microsoft Windows 7
Controlling software	FACSComp		AQUIOS System Software
Lasers	Blue – 488 nm argon ion Red – 635 nm diode laser		Blue – 488 nm Blue Laser (20mW)
Sample Preparation	Manual		Automated On-board
Lyse Timing	15 minute incubation in the dark at room temperature.		Less than or equal to 3 minutes in the dark at room temperature
Lyse Reagents	BD FACS lysing solution		AQUIOS Lysing Reagent Kit
Monoclonal Antibody Assay	BD Trucount tubes Two tube antibody reagent assay: o CD3-FITC/CD8-PE/CD45-PerCP/CD4-APC		Two tube monoclonal antibody reagent assay: o CD45-FITC/CD4-RD1/CD8-

Differences			
	Predicate FACSCalibur		**Device**
Characteristic	**CaliBRITE APC beads CaliBRITE 4 kit (unlabeled, FITC-, PE-, PerCP- and APC-labeled CaliBRITE beads), and FACSComp software**	**CaliBRITE 3 Color and FACSComp**	**AQUIOS CL Flow Cytometer**
	o CD3-FITC/CD16-PE+CD56-PE/CD45-PerCP/CD19-APC		ECD/CD3-PC5 o CD45-FITC/CD56+CD16-RD1/CD19-ECD/CD3-PC5
Specimen Introduction	N/A		Specimens are loaded in the Autoloader using cassettes / or the single loader as single specimen tubes
Prepared Sample Introduction	FACS Loader (K953302)		96 well plate
Specimen Identification	Manual entry into Worklist		Barcode – positive sample identification or manual entry
Prepared Sample Identification	Worklist and Carousel position		Software tracked by well position.
Standardization	• Automatic voltage/gain adjustments • Compensation matrix calculation		A standardization check is performed on each control run
Sample Analysis	Manual gating of cellular populations per instrument IFU or automated gating of cellular populations with BD Multiset software		Automated gating of cellular population by AQUIOS System Software. The software only allows region readjustments by the user
Count Method	Cellular events are compared to bead events. Automated method: Absolute counts are determined by MultiSET™ software. Manual data analysis using software such as CellQuest™, absolute counts are		Syringe based volumetric method using AQUIOS System Software

Differences			
	Predicate FACSCalibur		**Device**
Characteristic	**CaliBRITE APC beads CaliBRITE 4 kit (unlabeled, FITC-, PE-, PerCP- and APC-labeled CaliBRITE beads), and FACSComp software**	**CaliBRITE 3 Color and FACSComp**	**AQUIOS CL Flow Cytometer**
	determined by division of the number of positive cellular events by the number of bead events multiplied by the TruCOUNT bead concentration.		
Photomultipler Tubes (PMTs) / Colors	FSC Diode SSC 488/10 4 FL Detectors: • FL1 530/30 nm • FL2 585/42 nm • FL3 670 (LP) nm • FL4 661/16 nm		FS Solid State Detector SS Solid State Detector – (488LP Dichroic) 4 FL Detectors: • 525nm BP Filter • 575nm BP Filter • 620nm BP Filter • 675nm BP Filter
Detectors/ Parameters	Six (FS, SS, FL1-FL4)		Seven (EV, FS, SS, FL1 – FL4)
Off-line analysis software	BD Multiset and BD Cell Quest Pro		Stand-alone workstations with AQUIOS System Software to review data offline

AQUIOS Tetra-1 and Tetra-2+ Device Comparison Tables:

Similarities			
	Predicate		Device
Characteristic	**MultiTEST CD3/CD8/CD45/CD4**	**Multitest CD3/CD16+56/CD45/CD19 Reagent and Multitest IMK Kit Lysing Solution with BD TruCount Tubes (PREDICATE)**	**AQUIOS Tetra-1 and AQUIOS Tetra-2+**
Intended Use*	The BD Multitest IMK kit is a four-color direct immunofluorescence reagent kit for use with a suitably equipped flow cytometer to identify and determine the percentages and absolute counts of the following mature human lymphocyte subsets in erythrocyte-lysed whole blood: T lymphocytes (CD3+), B lymphocytes (CD19+), helper/inducer T lymphocytes (CD3+CD4+), suppressor/cytotoxic T lymphocytes (CD3+CD8+), and natural killer (NK) lymphocytes (CD3-CD16+ and /or CD56+). BD Trucount tubes are used for determining absolute counts. BD Multitest reagents and BD Trucount tubes can be used with the BD FACS Loader. * Only similar parameters of both devices are presented here. Refer to DxH 800 SE table for other parameters.		AQUIOS Tetra-1 Panel and AQUIOS Tetra-2+ Panel monoclonal antibody reagents are for use on the AQUIOS CL Flow Cytometer with peripheral whole blood for immunophenotyping. These reagents are indicated for use in the immunologic assessment of patients having, or suspected of having, immune deficiency. These reagents provide identification and enumeration of; - AQUIOS Tetra-1 Panel Monoclonal Antibody Reagent • Total CD3+, CD3+CD4+,CD3+CD8+, CD3+CD4+/CD3+CD8+ (ratio only) lymphocyte percentages and absolute counts. - AQUIOS Tetra-2+ Panel Monoclonal Antibody Reagent • Total CD3+, CD3-CD19+, CD3-CD56+ and/or CD16+ lymphocyte percentages and absolute counts.

Similarities			
	Predicate		Device
Characteristic	**MultiTEST CD3/CD8/CD45/CD4**	**Multitest CD3/CD16+56/CD45/CD19 Reagent and Multitest IMK Kit Lysing Solution with BD TruCount Tubes (PREDICATE)**	**AQUIOS Tetra-1 and AQUIOS Tetra-2+**
Device Classification	Class II		Same
Reagent Assay	BD Multitest CD3/CB8/CD45/CD4 reagent provided in 1 ml of buffered saline with 0.1% sodium azide	BD Multitest CD3/CD16+CD56/CD45/CD19 reagent provided in 1 ml of buffered saline with 0.1% sodium azide	Two test monoclonal antibody reagent assay: o CD45/CD4/CD8/CD3 o CD45/CD56+CD16/CD19/CD3

Differences			
	Predicate		Device
Characteristic	**MultiTEST CD3/CD8/CD45/CD4**	**Multitest CD3/CD16+56/CD45/CD19 Reagent and Multitest IMK Kit Lysing Solution with BD TruCount Tubes (PREDICATE)**	**AQUIOS Tetra 1 and AQUIOS Tetra-2+**
Product Code	GKZ		OYE
Instrument Quality Control Techniques	BD Multi-Check control, BD Multi-Check CD4 Low control and CaliBRITE Beads		AQUIOS Immuno-Trol and AQUIOS Immuno-Trol Low
Antibody Incubation Time	15 minutes in the dark at room temperature		15-45 minutes in the dark at room temperature

Similarities		
	Predicate	**Device**
Characteristic	**UniCel DxH 800**	**AQUIOS Tetra 1 and AQUIOS Tetra-2+**
Intended Use*	The UniCel® DxH 800 Analyzer is a quantitative multi-parameter, automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The UniCel® DxH 800 Analyzer **identifies and enumerates** the parameters indicated below on the following sample types: ▪ Whole Blood (Venous) o **WBC, LY%, LY#** * Only similar parameters of both devices are presented here	AQUIOS Tetra-1 Panel and AQUIOS Tetra-2+ Panel monoclonal antibody reagents are for use on the AQUIOS CL Flow Cytometer with peripheral whole blood. These reagents are indicated for use in the immunologic assessment of patients having, or suspected of having, immune deficiency. These reagents provide **identification and enumeration of**; - AQUIOS Tetra-1 Panel Monoclonal Antibody Reagent • **CD45+ absolute count** • **CD45+ Low SS (lymphocytes) percentage and absolute count** - AQUIOS Tetra-2+ Panel Monoclonal Antibody Reagent • **CD45+ absolute count** • **CD45+ Low SS (lymphocytes) percentage and absolute count**
Device Classification	Class II	Same
Specimen Age Claim	24 hours room temperature	Same

Similarities		
	Predicate	**Device**
Characteristic	**UniCel DxH 800**	**AQUIOS Tetra 1 and AQUIOS Tetra-2+**
Sample Preparation	Whole blood sample diluted with reagents	Same
Quality Control Techniques	Daily Instrument Checks Commercial Controls Inter-laboratory Quality Assurance Program (IQAP)	Daily Instrument Checks Commercial Controls Inter-laboratory Quality Assurance Program (IQAP)
Sampling Mechanism	Single aspiration probe used for all sampling. Single-tube presentation – open and closed vial sampling – specimen manually mixed Automated presentation – closed vial sampling from five-position cassette accepting a variety of defined specimen tubes. Cassette containing specimens mixed prior to starting sampling and between specimens.	Same
Mechanisms for Processing	Mechanisms to achieve process of : ▪ automated cassette transportation and specimen mixing (by rocking) ▪ sample aspiration ▪ sample preparation ▪ sample and reagent presentation to analytical modules ▪ sample analysis ▪ raw data collection ▪ algorithmic processing ▪ data reporting	Same

Differences		
	Predicate	**Device**
Characteristic	**UniCel DxH 800**	**AQUIOS Tetra-1 and AQUIOS Tetra-2+**
Intended Use	The UniCel® DxH 800 Analyzer is a quantitative multi-parameter, automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The UniCel® DxH 800 Analyzer identifies and enumerates the parameters indicated below on the following sample types: ▪ Whole Blood (Venous and Capillary) o RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, NE%, NE#, MO%, MO#, EO%, EO#, BA%, BA#, NRBC%, NRBC#, RET%, RET#, MRV, IRF ▪ Pre-Diluted Whole Blood (Venous and Capillary) o WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV ▪ Body Fluids (cerebrospinal, serous and synovial) o TNC and RBC	AQUIOS Tetra-1 Panel and AQUIOS Tetra-2+ Panel monoclonal antibody reagents are for use on the AQUIOS CL Flow Cytometer with peripheral whole blood. These reagents are indicated for use in the immunologic assessment of patients having, or suspected of having, immune deficiency. These reagents provide identification and enumeration of; - AQUIOS Tetra-1 Panel Monoclonal Antibody Reagent • Total CD3+, CD3+CD4+,CD3+CD8+, CD3+CD4+/CD3+CD8+ (ratio only) lymphocyte percentages and absolute counts. - AQUIOS Tetra-2+ Panel Monoclonal Antibody Reagent • percentage and absolute count • Total CD3+, CD3-CD19+, CD3-CD56+ and/or CD16+ lymphocyte percentages and absolute counts. AQUIOS Flow Cytometry Software may be run on an independent computer workstation for off-line analysis of results generated by the AQUIOS CL Flow Cytometer with the monoclonal antibody reagents listed above. The off-line analysis must be performed in accordance with the product labeling.

Differences		
	Predicate	**Device**
Characteristic	**UniCel DxH 800**	**AQUIOS Tetra-1 and AQUIOS Tetra-2+**
Product Code	GKZ	OYE
Specimen Age Claim	48 hours refrigerated	Should not be refrigerated.
WBC, RBC, MCV, Plt, TNC	Aperture impedance (Coulter® Principle)	Aperture impedance (Coulter® Principle) and flow cytometry analysis
Performance Characteristics	Quantitative test for RBC, HGB, HCT, MCV, MCHC, RDW, RDW-SD, PLT, MPV, NE%, NE#, MO%, MO#, EO%, EO#, BA%, BA#, NRBC%, NRBC#, RET%, RET#, MRV, IRF, TNC	Total CD3+, CD3+CD4+,CD3+CD8+, CD3+CD4+/CD3+CD8+ (ratio only), CD3-CD19+, CD3-CD56+ and/or CD16+ lymphocyte percentages and absolute counts.
Reagents to determine Lymphocytes	Coulter® DxH Diluent Coulter® DxH Diff Pack	AQUIOS Tetra-1 - CD45-FITC, B3821F4A; CD4-RD1, SFCI12T4D11; CD8-ECD, SFCI21Thy2D3; CD3-PC5, UCHT1 AQUIOS Tetra-2+ - CD45-FITC, B3821F4A; CD3-PC5, UCHT1; CD56+CD16-RD1, N901/NKH-1;CD19-ECD, J3-119 AQUIOS Lysing Reagent Kit AQUIOS Sheath
Reagents to determine WBC	Coulter® DxH Diff Pack Coulter® DxH Cell Lyse	AQUIOS Tetra-1 - CD45-FITC, B3821F4A; CD4-RD1, SFCI12T4D11; CD8-ECD, SFCI21Thy2D3; CD3-PC5, UCHT1 AQUIOS Tetra-2+ - CD45-FITC, B3821F4A; CD3-PC5, UCHT1; CD56+CD16-RD1, N901/NKH-1;CD19-ECD, J3-119 AQUIOS Lysing Reagent Kit AQUIOS Sheath
Controls	Coulter® 6C Cell Control Coulter® Latron™ CP-X Control	AQUIOS Immuno-Trol Cells AQUIOS Immuno-Trol Low Cells
Calibrators	Coulter® S-CAL® Calibrator Kit	Factory/Service calibrated

AQUIOS Immuno-Trol and Immuno-Trol Low Cells Device Comparison Tables:

Similarities			
	Predicate		Device
Characteristic	**Immuno-Trol Control Cells (Predicate)**	**Immuno-Trol Low Cells (Predicate)**	**AQUIOS Immuno-Trol and Immuno-Trol Low**
Intended Use	IMMUNO-TROL™ Control Cells (Immuno-Trol) is an assayed, lysable whole blood quality control product for immunophenotyping analysis using monoclonal antibody reagents and flow cytometry. It provides a positive cell control that is processed in the same manner as a whole blood sample. This allows verification of reagent performance and the methods used for staining targeted cells, lysing erythrocytes, and analyzing samples by flow cytometry.	IMMUNO-TROL™ Low Cells is an assayed, lysable whole blood quality control product for immunophenotyping analysis using monoclonal antibody reagents and flow cytometry. It provides a positive cell control that is processed in the same manner as a whole blood sample.	AQUIOS Immuno-Trol AQUIOS IMMUNO-TROL™ Cells are assayed, lysable whole blood quality control product for immunophenotyping analysis using monoclonal antibody reagents and flow cytometry. It provides a positive cell control that is processed in the same manner as a whole blood sample. This allows verification of instrument and reagent performance. It also verifies the methods used for staining targeted cells, lysing erythrocytes, and analyzing samples by the AQUIOS CL Flow Cytometer. AQUIOS Immuno-Trol Low AQUIOS IMMUNO-TROL™ Low Cells are assayed, lysable whole blood quality control product for immunophenotyping analysis using monoclonal antibody reagents and flow cytometry. It provides a positive cell control that is processed in the same manner as a whole blood sample. This allows verification of instrument and reagent performance. It also verifies the methods used for staining targeted cells, lysing erythrocytes, and analyzing samples by the AQUIOS CL Flow Cytometer.

Similarities			
	Predicate		Device
Characteristic	**Immuno-Trol Control Cells (Predicate)**	**Immuno-Trol Low Cells (Predicate)**	**AQUIOS Immuno-Trol and Immuno-Trol Low**
Device Classification and Product Code	Class II, JPK		Same

Differences			
	Predicate		Device
Characteristic	**Immuno-Trol Control Cells (Predicate)**	**Immuno-Trol Low Cells (Predicate)**	**AQUIOS Immuno-Trol and Immuno-Trol Low**
Assay Parameters	CD3+ count, % CD3+/CD4+ count, % CD3+/CD8+ count, % CD3-/CD56+ count, % CD19+ count, %		Same except with the addition of; CD3-/(CD56+16)+ count, % CD45+ count CD45+ Low SS count, % CD3 Separation Quotient CD4 Separation Quotient CD8 Separation Quotient CD56+16 Separation Quotient CD19 Separation Quotient CD45 Lymph/High SS Cells Separation Quotient SS Lymph/High SS Cells Separation Quotient FS Lymph/High SS Separation Quotient

Summary of AQUIOS CL Flow Cytometer Performance Testing

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Fluorescence Linearity	Verify fluorescence detection is linear using standard AQUIOS Tetra settings.	None	None	Linearity of fluorescence measurements was demonstrated.
Electronic Volume Linearity	Verify linearity of Electronic Volume measurements at the standard AQUIOS Tetra settings.	None	None	Linearity of Electronic Volume measurements was demonstrated.
Laser Performance Characteristics	Verify stability of the laser performance of the AQUIOS CL flow cytometer over time.	None	None	Analysis of the data collected demonstrates that the AQUIOS CL laser performance is stable over time.
Analyzer Carryover	To verify carryover for whole blood 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 AQUIOS CL meets the whole blood carryover performance requirements.

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Instrument Settings Stability	Testing to demonstrate stability of the AQUIOS instrument settings to support adequacy of the quality control methodology as an indicator of instrument performance.	None	None	Analysis of the data collected demonstrate that the stability of the AQUIOS CL instrument settings support the quality control methodology.
Gravimetrics	Evaluate accuracy and precision of dispensing AQUIOS lysing and antibody reagents, and specimen aspiration/dispense.	None	None	Analysis of the data collected demonstrates accuracy and precision of dispensing AQUIOS lysing and antibody reagents, and specimen aspiration/dispense.
Comparability - Collection Tube Performance	Evaluate tube characteristics when used on the AQUIOS system. Study will include verification of the dispensed specimen volumes and minimum required aspiration volumes across the different tube types. Results obtained with the different tube types will be compared at the minimum and maximum number of pierces.	None	CLSI EP15-A2, User Verification of Performance for Precision and Trueness; Approved Guideline – Second Edition. (FDA Recognition Number 7-153)	Analysis of the data collected verified the specimen tube recommendations in product labeling.

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 AQUIOS CL 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 AQUIOS CL meets the linearity performance requirements.
Assay Carryover	To verify carryover of whole blood and reagents on the AQUIOS CL 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 AQUIOS CL meets carryover performance requirements.
Detection Capability	To verify that the AQUIOS CL meets the performance requirements for Limit of Blank (LoB), Lower Limit of Detection (LLoD), Lower 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 AQUIOS CL meets the performance requirements for LoB, LLoD, and LLoQ in whole blood.

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
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 AQUIOS CL Flow Cytometry System meets the requirements for specimen and prepared sample stability.
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 AQUIOS CL Flow Cytometry System meets the performance requirements when compared to the predicate device.
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 EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.	Analysis of the data collected demonstrates that the AQUIOS CL meets performance requirements for Long Term Imprecision.

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
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	Analysis of the data collected demonstrates that the AQUIOS CL meets performance requirements for Whole Blood Repeatability.
Comparability (Equivalency) – Anticoagulant, Sample Presentation Mode, Open and Closed Vial Sampling Modes, Test Panel Equivalency	Provide data on equivalency of anticoagulants, modes, and panels for use on AQUIOS system.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Accuracy (Section 8)	CLSI EP09-A3, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline--Second Edition (Interim Revision)	For all conditions evaluated, the data collected demonstrates that the AQUIOS CL within-method comparisons are equivalent.
Adult Reference Intervals	Establish adult reference intervals for lymphocyte subset analysis on the AQUIOS system.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells – Reference Values (Section 14)	C28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory	Adult reference intervals were established and confirmed to be consistent with published values for T, B, and NK lymphocyte subsets.

Summary of AQUIOS Tetra-1 and Tetra-2+ Performance Testing:

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Stability	Stability testing will demonstrate the shelf life of the reagents.	None	CLSI EP25-A – Evaluation of Stability of In Vitro Diagnostic Reagents. Approved Guideline	Analysis of the data collected demonstrates that the AQUIOS Tetra-1 and Tetra-2+ reagents meet performance requirements in support of the product's stability claims.
Lot Variability	Variability of multiple lots of material was incorporated into the overall system variability assessed in the clinical testing.	None	CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.	Analysis of the data collected demonstrates that the AQUIOS Tetra-1 and Tetra-2+ have acceptable lot variability performance.

Summary of AQUIOS Immuno-Trol and Immuno-Trol Low Performance Testing:

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Assay Value Assignment and Expected Ranges	Determine the expected ranges (count, percent, separation quotient) for both levels of control as well as the process to assign these values to each lot of material.	None	None	Assay value assignment process and expected ranges were established and verified based on analysis of the data collected.
Stability	Stability testing will demonstrate the shelf life of the reagents.	None	CLSI EP25-A – Evaluation of Stability of In Vitro Diagnostic Reagents. Approved Guideline	Analysis of the data collected demonstrates that the AQUIOS Immuno-Trol and Immuno-Trol Low meet performance requirements in

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
				support of the product's stability claims.
Lot Variability	Verify lot variability of AQUIOS Immuno-Trol and Immuno-Trol Low.	None	CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.	Analysis of the data collected demonstrates that the AQUIOS Immuno-Trol and Immuno-Trol Low have acceptable lot variability performance.

Summary of AQUIOS Lysing Reagent Kit Performance Testing:

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Stability	Stability testing will demonstrate the shelf life of the reagents.	None	CLSI EP25-A – Evaluation of Stability of In Vitro Diagnostic Reagents. Approved Guideline	Analysis of the data collected demonstrates that the AQUIOS Lyse reagents meet performance requirements in support of the product's stability claims.
Lot Variability	Variability of multiple lots of material was incorporated into the overall system variability assessed in the clinical testing.	None	CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.	Analysis of the data collected demonstrates that the AQUIOS Tetra-1 and Tetra-2+ have acceptable lot variability performance.

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

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

- The AQUIOS CL Flow Cytometer and AQUIOS Tetra-1 and Tetra-2+ reagents are substantially equivalent to the FACSCalibur CaliBRITE 4 kit and FACSComp Software as well as the UniCel DxH 800, where applicable.
- The AQUIOS Immuno-Trol and Immuno-Trol Low are substantially equivalent to Immuno-Trol Cells and Immuno-Trol Low Cells.

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.