September 28, 2020

Becton, Dickinson and Company
Niya Su
Senior Manager, Regulatory Affairs
2350 Qume Drive
San Jose, California 95131

Re: K201814
Trade/Device Name: BD FACSLyric Flow Cytometer
BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation System
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: OYE
Dated: June 30, 2020
Received: July 1, 2020

Dear Niya Su:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to 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 (Katelin) Mao, PhD
Chief
Division of Immunology
and Hematology Devices
OHT7: Office of In Vitro Diagnostics
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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201814

Device Name
BD FACSLyric™ Flow Cytometer

Indications for Use *(Describe)*
The BD FACSLyric™ flow cytometer is intended for use as an in vitro diagnostic device for immunophenotyping using up to six fluorescence detection channels and two light scatter channels using a blue (488-nm) and a red (640-nm) laser. 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.

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

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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201814

Device Name
BD FACSLyric™ Flow Cytometer with the integrated BD FACSDuet™ Sample Preparation System

Indications for Use *(Describe)*
The BD FACSLyric™ flow cytometer with the integrated BD FACSDuet™ Sample Preparation System is intended for use as an in vitro diagnostic device for immunophenotyping using up to six fluorescence detection channels and two light scatter channels using a blue (488-nm) and a red (640-nm) laser. It includes an automated sample preparation system used to prepare human peripheral whole blood samples for acquisition and analysis and 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)

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510(k) Summary

This 510(k) summary is being provided in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Date of Summary: August 31, 2020

1. Submitted By

BD Biosciences
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2. Device

Trade Name/Device Name:

- BD FACSLyric™ Flow Cytometer
- BD FACSLyric™ Flow Cytometer with the integrated BD FACSDuet™ Sample Preparation System

Classification: Class II
Device Classification: Flow Cytometric Reagents and Accessories
Regulation Description: Automated Differential Cell Counter
Regulation Medical Specialty: Hematology
Product Code: OYE
Regulation Number: 21 CFR 864.5220

3. Predicate Device

Trade Name/Device Name: BD FACSLyric™ Flow Cytometer

Classification: Class II
Device Classification: Flow Cytometric Reagents and Accessories
Regulation Description: Automated Differential Cell Counter
Regulation Medical Specialty: Hematology
Product Code: OYE
Regulation Number: 21 CFR 864.5220

4. Device Modification

Table 1 contains an overview of FACSLyric flow cytometer system components and device modification covered by this 510(k).

Table 1. FACSLyric Flow Cytometer System Components and Device Modification

System component	Cleared in K170974	Modification of this Special 510(k)
BD FACSLyric™ Flow Cytometer	Yes	Modified
BD FACS™ Universal Loader	Yes	Modified
BD FACSuite™ Clinical software	Yes	Modified
BD FACSDuet™ Sample Preparation System (hereinafter referred to as FACSDuet instrument)	No	Modified (new instrument)
BD Multitest™ 6- Color and 4-Color Assay Modules	Yes	Not affected
BD FACSFlow™ Sheath Fluid	Yes	
BD® CS&T Beads	Yes	
BD® FC Beads 7-Color Kit	Yes	

The cleared FACSLyric flow cytometer will be modified as follows:

- Modification 1: Minor changes to FACSuite Clinical software, FACSLyric Cytometer Management System (CMS) firmware and FACS Universal Loader hardware to allow for the integration with FACSDuet instrument.
- Modification 2: The addition of FACSDuet instrument as an optional automated sample preparation accessory to FACSLyric Flow Cytometer.

The intended/indications for use, fundamental scientific technology, acquisition and analysis on FACSLyric flow cytometer system are the same as the predicate device.

FACSDuet instrument is an automated sample preparation instrument that is data integrated with FACSLyric flow cytometer, and may also be physically integrated. It is an optional accessory to the FACSLyric flow cytometer system. FACSDuet instrument will be used with BD Multitest reagents (which utilized the FDA's draft guidance, *Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices*, issued on December 18, 2017) for use on FACSLyric flow cytometer.

5. Indications for Use

5.1 BD FACSLyric Flow Cytometer, FACS Universal Loader, FACSuite Clinical Software, Multitest 6-Color and 4-Color Assay Modules, FACSFlow Sheath Fluid, and CS&T Beads

The same as the predicate device.

5.2 BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation System

The BD FACSLyric flow cytometer with the integrated BD FACSDuet Sample Preparation System is intended for use as an in vitro diagnostic device for immunophenotyping using up to six fluorescence detection channels and two light scatter channels using a blue (488-nm) and a red (640-nm) laser. It includes an automated sample preparation system used to prepare human peripheral whole blood samples for acquisition and analysis and is intended for use with in vitro diagnostic (IVD) assays and software that are indicated for use with the instrument.

5.3 BD FC Beads 7-Color Kit

The same as the predicate device with minor correction in the statement.

The BD FC Beads 7-Color kit (BD FC Beads), in conjunction with BD FACSuite Clinical software and BD CS&T beads, is used to establish fluorescence compensation for the BD FACSLyric flow cytometer.

6. Multiple Functions Device

The following statement is provided, according to the FDA draft guidance, *Multiple Function Device Products: Policy and Considerations*, dated April 27, 2018.

The products have functions subject to FDA premarket review and functions that are not subject to FDA premarket review. For this application, FDA assessed functions not subject to premarket review only insofar as they might adversely impact the safety and effectiveness of the functions subject to FDA premarket review.

7. Substantial Equivalence Comparison between Subject Devices and Predicate Device

A comparison of the similarities and differences between the subject devices and the predicate device is presented in Table 2**.**

Table 2. Comparison Between Predicate Device and Subject Devices

Feature/Attribute	Predicate Device FACSLyric Flow Cytometer (K170974)	Subject Device/Modified Device FACSLyric Flow Cytometer	Subject Device/Modified Device FACSLyric Flow Cytometer with the integrated FACSDuet Sample Preparation System
Flow Cytometer System			
Device Classification and Product Code	• Automated Differential Cell Counter • Regulatory Class: II • Regulation Number: 21 CFR 864.5220 • Product Code: OYE	Same	Same
Assay Methodology	Flow Cytometry	Same	Same
Detection/Assay Principle	Immunofluorescence	Same	Same
Intended Use/Indications for Use	The BD FACSLyric flow cytometer is intended for use as an in vitro diagnostic device for immunophenotyping using up to six fluorescence detection channels and two light scatter channels using a blue (488-nm) and a red (640-nm) laser. It is intended for use with in vitro diagnostic (IVD) assays* and software that are indicated for use with the instrument.	Same	The BD FACSLyric™ flow cytometer **with the integrated BD FACSDuet™ Sample Preparation System** is intended for use as an in vitro diagnostic device for immunophenotyping using up to six fluorescence detection channels and two light scatter channels using a blue (488-nm) and a red (640-nm) laser. **It includes an automated sample preparation system used to prepare human peripheral whole blood samples for acquisition and analysis** and is intended for use with in vitro diagnostic (IVD) assays and software that are indicated for use with the instrument.
Specimen Type	Peripheral whole blood	Same	Same
Sample Volume	50 µL	Same	Same

Feature/Attribute	Predicate Device FACSLyric Flow Cytometer (K170974)	Subject Device/Modified Device FACSLyric Flow Cytometer	Subject Device/Modified Device FACSLyric Flow Cytometer with the integrated FACSDuet Sample Preparation System
Optical Configurations	• 2-laser (blue, red), 4-color (3-1) • 2-laser (blue, red), 6-color (4-2) • 3-laser (blue, red, violet), 8-color (4-2-2) • 3-laser (blue, red, violet), 10-color (4-3-3) Only up to six detection channels using red and blue lasers are for IVD use	Same, **plus additional 3 laser (blue, red, violet), 12-color (4-3-5) configuration**	Same, **plus additional 3 laser (blue, red, violet), 12-color (4-3-5) configuration**
Maximum Parameter Detectors	IVD detection channels – Six Fluorescence channels plus forward scatter and side scatter	Same	Same
IVD Lasers/Excitation	Blue Laser: • Wavelength: 488 nm • Optical power: 20mW Red Laser: • Wavelength: 640 nm • Optical power: 40 mW	Same	Same
Electronics	Up to 35000 events, sec	Same	Same
Forward Scatter Detection	Photodiode with built in 488/10 bandpass filter	Same	Same

Feature/Attribute	Predicate Device FACSLyric Flow Cytometer (K170974)	Subject Device/Modified Device FACSLyric Flow Cytometer	Subject Device/Modified Device FACSLyric Flow Cytometer with the integrated FACSDuet Sample Preparation System
Fluorescence and Side Scatter Detection	Side scatter and fluorescence • Reflective optics with single transmission bandpass filter in front of each PMT • High performance PMT modules for all fluorescence and side scatter channels • Light collected by objective lens is delivered by fiber optics especially designed detector arrays • The cuvette flow cell is gel-coupled by refractive index-matching optical gel to the fluorescence objective lens (1.2 NA) for optimal collection efficiency	Same	Same
Fluidics	FACSLyric Flow Cytometer fluidics - • Uses FACSFlow as the sheath fluid • Uses 10% bleach solution for system cleaning	Same	• FACSLyric Flow Cytometer fluidics Same • **FACSDuet fluidics –** **Saline: used for washing the specimen probe** **DI water: used for washing the reagent and specimen probes** **10% bleach solution: used for cleaning the specimen probe during the FACSDuet End of Day Clean task**
Software	FACSuite Clinical software	**Modified** FACSuite Clinical software (same software as FACSLyric with FACSDuet)	• **Modified** FACSuite Clinical software • **FACSDuet software**

Feature/Attribute	Predicate Device FACSLyric Flow Cytometer (K170974)	Subject Device/Modified Device FACSLyric Flow Cytometer	Subject Device/Modified Device FACSLyric Flow Cytometer with the integrated FACSDuet Sample Preparation System
Firmware	CMS firmware	**Modified** CMS Firmware (same firmware as FACSLyric with FACSDuet)	• **Modified** CMS Firmware • **FACSDuet firmware**
Loader	FACS Universal Loader	**Modified** FACS Universal Loader. **Changes are listed below:** • **Updated shaker to have a more robust mechanism for the gripper fingers which hold on to the sample carrier;** • **Modification to the door lock and sensor connections to enable automated transfer of sample carriers from FACSDuet to FACSLyric**	**Modified** FACS Universal Loader. **Changes are listed below:** • **Updated shaker to have a more robust mechanism for the gripper fingers which hold on to the sample carrier;** • **Modification to the door lock and sensor connections to enable automated transfer of sample carriers from FACSDuet to FACSLyric;** • **Replacement of the loader outside cover (skins) and window, including relocation of loader label and status light (for physical integration only);** • **Addition of a stabilization bracket connecting FACS Universal Loader to FACSDuet instrument (for physical integration only.)**
Results Reporting	Software-assisted report generation	Same	Same

Feature/Attribute	Predicate Device FACSLyric Flow Cytometer (K170974)	Subject Device/Modified Device FACSLyric Flow Cytometer	Subject Device/Modified Device FACSLyric Flow Cytometer with the integrated FACSDuet Sample Preparation System
Sample Introduction	• Manual loading onto the tube port of the flow cytometer • Automated loading through a multi-tube FACS Universal Loader	Same	FACSLyric flow cytometer is not physically integrated with FACSDuet Sample Preparation System: Same **FACSLyric flow cytometer is physical integrated with FACSDuet Sample Preparation System:** Same, **plus FACSDuet instrument automatically transferring the 30 or 40-tube sample carrier to the modified FACS Universal Loader of FACSLyric flow cytometer**
Sample Preparation	Manual	Same	**Automated with FACSDuet Sample Preparation System**
Pipetting	Manual Sample Preparation: Reverse pipetting for peripheral blood	Same	**Automated Sample Preparation**
Specimen Tube Mixing	Manual Sample Preparation: Mixing manually	Same	**Automated Sample Preparation**
Sample Tube Mixing	Manual Sample Preparation: Mixing manually	Same	**Automated Sample Preparation**
Incubation Time	Manual Sample Preparation: 15 minutes	Same	**15 minutes – 30 minutes**

Feature/Attribute	Predicate Device FACSLyric Flow Cytometer (K170974)	Subject Device/Modified Device FACSLyric Flow Cytometer	Subject Device/Modified Device FACSLyric Flow Cytometer with the integrated FACSDuet Sample Preparation System
Dimensions	Cytometer (W x D x H) 63.3 x 57.9 x 57.9 cm (24.93 x 22.8 x 22.8 in)	Same	**Cytometer with FACSDuet instrument including FACSLyric workstation (W x D x H)** **282.9 x 77.1 x 85.0 cm** **(111.4 x 30.4 x 33.5 in)**
Quality Control and Setup Beads			
Intended Use/Indications for Use	**BD FC beads 7-color kit** The BD FC beads 7-color kit (BD FC beads), in conjunction with BD FACSuite Clinical software and BD CS&T beads, **are** used to establish fluorescence compensation for the BD FACSLyric flow cytometer. **BD CS&T beads** BD CS&T beads, in conjunction with BD FACSuite Clinical software, provide a standardized method for the quality control of optics, electronics, and fluidics, and for adjusting detector voltages and fluorescence compensation on the BD FACSLyric flow cytometer.	**BD FC beads 7-color kit** Same with minor correction. The BD FC beads 7-color kit (BD FC beads), in conjunction with BD FACSuite Clinical software and BD CS&T beads, **is** used to establish fluorescence compensation for the BD FACSLyric flow cytometer. **BD CS&T beads** Same	**BD FC beads 7-color kit** Same with minor correction. The BD FC beads 7-color kit (BD FC beads), in conjunction with BD FACSuite Clinical software and BD CS&T beads, **is** used to establish fluorescence compensation for the BD FACSLyric flow cytometer. **BD CS&T beads** Same

Feature/Attribute	Predicate Device FACSLyric Flow Cytometer (K170974)	Subject Device/Modified Device FACSLyric Flow Cytometer	Subject Device/Modified Device FACSLyric Flow Cytometer with the integrated FACSDuet Sample Preparation System
Quality Control & Instrument Setup	• Daily QC performed using CS&T beads. • QC is also preformed every 6 months using CS&T beads. It includes all of the measurements performed in daily QC along with additional more detailed measurements and an automatic laser alignment. • Daily instrument setup using CS&T beads. • FC Beads are run every 2 months to measure and reset instrument spectral overlap values as part of the instrument setup.	Same	• FACSLyric flow cytometer: Same • **FACSDuet instrument:** - **Initialization** - **Verification of dispense accuracy and precision** - **Process controls: Multi-Check Control and Multi-Check CD4 Low Control**

The modified devices are the same as the predicate device as follows:

- The intended/indications for use, fundamental scientific technology, acquisition and analysis on FACSLyric flow cytometer system
- The intended/indications for use of the CS&T and FC 7-Color beads and the Quality Control and Instrument Setup on FACSLyric flow cytometer
- Sample preparation steps

The modified devices differ from the predicate device as follows:

- Adds an accessory, FACSDuet instrument, to automate sample preparation and transfer to FACSLyric flow cytometer for acquisition (applicable to the subject device FACSLyric with the integrated FACSDuet system only)

- Minor changes to the CMS firmware, FACS Universal Loader hardware and FACSuite Clinical software to allow for the integration with FACSDuet instrument.

8. Performance Data

8.1 Performance of Modified FACSLyric Flow Cytometer

From the predicate FACSLyric flow cytometer to the modified FACSLyric flow cytometer (subject device), system verification and validation testing was conducted to demonstrate the equivalent performance between the upgraded and previous released product.

8.2 Performance of FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation System

The following analytical (Table 3) and clinical (Table 4) performance data were provided to support the determination of substantial equivalency between the FACSLyric with the integrated FACSDuet system (subject device) and the FACSLyric flow cytometer (predicate device).

Table 3. Analytical Performance Summary

Study	Standard	Objective	Results
Within-site Precision	*CLSI EP05-A3*	To evaluate the within-site precision performance of FACSLyric flow cytometer with FACSDuet instrument.	All acceptance criteria were met.
Whole Blood Repeatability	*CLSI EP05-A3*	To verify repeatability performance of FACSLyric flow cytometer with FACSDuet instrument using HIV+ patient and normal whole blood specimens.	Repeatability performance was demonstrated across all the instruments.
Linearity	*CLSI EP6-A*	To evaluate the linear range of FACSLyric flow cytometer with FACSDuet instrument.	The linear range of FACSLyric flow cytometer with FACSDuet instrument was established based on the acceptance criteria.
Limit of Blank (LoB) and Limit of Detection (LoD)	*CLSI EP17-A2*	To evaluate the LoB and LoD of FACSLyric flow cytometer with FACSDuet instrument.	LoB and LoD of FACSLyric flow cytometer with FACSDuet instrument were established, and met the acceptance criteria.
Limit of Quantitation (LoQ)	*CLSI EP17-A2*	To evaluate the LoQ of FACSLyric flow cytometer with FACSDuet instrument.	LoQ of the FACSLyric flow cytometer with the FACSDuet instrument was established, and met the acceptance criteria.

Study	Standard	Objective	Results
In-Use Reagent Stability Performance	*CLSI EP25-A*	To evaluate the in-use reagent stability of the Multitest 6-Color TBNK in the FACSDuet instrument.	All acceptance criteria were met.
Equivalency between 15 and 30 minutes Incubation Time	*N/A*	To demonstrate equivalency between 15 and 30 minutes staining incubation time using manual and FACSDuet sample preparation.	All acceptance criteria were met.
Specimen Carryover	*CLSI H26-A2*	To evaluate the specimen to specimen and bleach to specimen carryover in FACSDuet instrument	All acceptance criteria were met.
Reagent Carryover	*N/A*	To evaluate the reagent carryover in FACSDuet instrument.	All acceptance criteria were met.
Pipette Dispense Accuracy and Precision	*N/A*	To evaluate the dispense accuracy and precision performance of FACSDuet instrument	All acceptance criteria were met.

Table 4. Clinical Performance Summary

Study	Standard	Testing Approach	Results
Method Comparison	*CLSI EP09c*	To evaluate performance equivalency between FACSLyric flow cytometer with FACSDuet instrument (subject device), and FACSLyric flow cytometer with manual sample preparation (predicate device).	A total of 399 enrolled specimens were tested across 3 sites. 29 samples were non-evaluable. The acceptance criteria were met.
Inter-laboratory Reproducibility	*CLSI EP05-A3*	To evaluate inter-laboratory reproducibility for FACSLyric flow cytometer with FACSDuet instrument.	The results demonstrated that the variability across three sites, and results met the acceptance criteria.

9. Conclusion

The subject/modified devices, BD FACSLyric™ Flow Cytometer and BD FACSLyric™ Flow Cytometer with the integrated BD FACSDuet™ Sample Preparation System, demonstrate substantial equivalency to the predicate device, BD FACSLyric™ Flow Cytometer.