U.S. FOOD & DRUG ADMINISTRATION

September 1, 2023

Beckman Coulter, Inc.
Attention: Patricia Zenelaj
Senior Manager, Regulatory Affairs
11800 SW 147th Avenue
Miami, FL 33196

Re: BK230961
Trade/Device Name: AQUIOS CL Flow Cytometer and AQUIOS Stem Kit
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Common Name: Flow Cytometric Reagents and Accessories
Regulatory Class: Class II
Product Code: OYE
Dated: May 30, 2023
Received: June 5, 2023

Dear Ms. Zenelaj:

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: CBER 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), 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,

Laura Ricles, PhD
Director
Division of Cell Therapy 2
Office of Cellular Therapy and Human Tissue
Office of Therapeutic Products
Center for Biologics Evaluation and Research

Enclosure: Indications for Use

Indications for Use (CBER/OTP)

510(k) Number: BK230961

Device Name: AQUIOS CL Flow Cytometer and AQUIOS Stem Kit

Indications for Use:

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

AQUIOS STEM Kit
The AQUIOS STEM Kit is an in vitro diagnostic medical device intended to be used by laboratory professionals for the simultaneous identification and enumeration of percent (%) CD34+ cell population, CD34+ cells/ul, and CD45+ cells/ul in fresh peripheral or mobilized peripheral whole blood, fresh or thawed bone marrow, fresh or thawed apheresis products, and fresh or thawed cord blood on the automated AQUIOS CL Flow Cytometry System.

Prescription Use _X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____
Concurrence of CBER, Office of Therapeutic Products

_____
Office Sign-Off
Office of Therapeutic Products

510(k):___BK230961_____