



**SUBSTANTIALLY EQUIVALENT**

December 15, 2021

Beckman Coulter Inc.  
Attn: Oilda Rubio  
Staff Regulatory Affairs Specialist  
11800 SW 147 Avenue  
M/S 31-K21  
Miami, FL 33196-2500

Re: BK210639

Trade/Device Name: Stem Kit Reagents, stemCXP System

Regulation Number: 21 CFR 864.5220

Regulation Name: Automated differential cell counter

Regulatory Class: Class II

Product Code: GKZ

Dated: October 4, 2021

Received: October 4, 2021

Dear Ms. Rubio:

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 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Wilson W. Bryan, MD  
Director  
Office of Tissues and Advanced Therapies  
Center for Biologics Evaluation and Research

Enclosure

**Indications for Use (CBER/OTAT)**

510(k) Number : BK210639/0

Device Name: Stem-Kit Reagents, stemCXP System

**Indications for Use:**

Stem-Kit Reagents consist of a two-color fluorescent (FITC, PE) murine monoclonal antibody reagent, a two-color murine fluorescent (FITC, PE) isoclonic control, an absolute count reagent, a cell viability reagent, and a lysing reagent. It is intended “For In Vitro Diagnostic Use” for the simultaneous identification and enumeration of CD45+ and dual-positive CD45+ CD34+ cell population percentages and absolute counts in biological specimens by flow cytometry. Biological specimens include fresh normal or mobilized peripheral whole blood, and fresh or thawed apheresis products, cord blood and bone marrow. Cell population measurements may be obtained using either an automated method or a manual method for gating and analysis. Refer to this Stem-Kit Reagents package insert for complete instructions if using the manual method. Refer to the stemCXP System Guide provided with the stemCXP for complete instructions if using the automated method.

The stemCXP SYSTEM, comprised of stemCXP Software for FC 500 flow cytometry systems with CXP software, Stem-Kit Reagents, quality control and standardization reagents, provides automated analysis of cell populations in fresh peripheral or mobilized peripheral whole blood, fresh bone marrow, and fresh or thawed apheresis products and cord blood. The stemCXP SYSTEM is intended for In Vitro Diagnostic Use to simultaneously identify and enumerate CD45+ and CD45+/CD34+ dual-positive cell populations.

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)

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Concurrence of CBER, Office of Tissues and Advanced Therapies

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Office Sign-Off  
Office of Tissues and Advanced Therapies

510(k): BK210639/0