



November 29, 2018

bioMérieux, Inc.
Attention: Ms. Mary Beth Anheuser
55 Anglum Road
Hazelwood, MO 63042

Re: BK180266
Device Name: BACT/ALERT® BPA Culture Bottle
BACT/ALERT® BPN Culture Bottle
Regulation Number: 21 CFR 866.2560
Regulation Name: Microbial growth monitor
Regulatory Class: I
Product Code: MZC
Dated: September 27, 2018
Received: October 1, 2018

Dear Ms. Anheuser:

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 (the 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.

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 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.

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 more information.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Orieji Illoh, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosure
Indications For Use

Indications for Use

510(k) Number: BK180266

Device Name: BACT/ALERT® BPA Culture Bottle
BACT/ALERT® BPN Culture Bottle

Indications for Use:

BPA Culture Bottle

BACT/ALERT® BPA culture bottles are used with the BACT/ALERT® Microbial Detection Systems for quality control testing of leukocyte reduced apheresis platelet (LRAP) units, and both leukocyte reduced single and a pool of up to six (6) units of leukocyte reduced whole blood platelet concentrates (LRWBPC). BACT/ALERT® BPA culture bottles support the growth of aerobic microorganisms (bacteria and fungi).

For the BACT/ALERT® 3D Systems, the following platelet preparation methods have been validated: leukocyte-reduced apheresis platelet (LRAP) units and both single and pools of up to six (6) units of leukocyte-reduced whole blood platelet concentrates (LRWBPC).

For the BACT/ALERT® VIRTUO® System, the following platelet preparation methods have been validated: leukocyte-reduced apheresis platelet (LRAP) units.

BPN Culture Bottle

BACT/ALERT® BPN culture bottles are used with the BACT/ALERT® Microbial Detection Systems for quality control testing of leukocyte reduced apheresis platelet (LRAP) units, and both leukocyte reduced single and a pool of up to six (6) units of leukocyte reduced whole blood platelet concentrates (LRWBPC). BACT/ALERT® BPN culture bottles support the growth of anaerobic and facultative anaerobic microorganisms (bacteria).

For the BACT/ALERT® 3D Systems, the following platelet preparation methods have been validated: leukocyte-reduced apheresis platelet (LRAP) units and both single and pools of up to six (6) units of leukocyte-reduced whole blood platelet concentrates (LRWBPC).

For the BACT/ALERT® VIRTUO® System, the following platelet preparation methods have been validated: leukocyte-reduced apheresis platelet (LRAP) units.

BACT/ALERT Microbial Detection Systems and culture bottles may be used for quality control testing of platelets and as a secondary safety measure test. Bacterial tests are labeled as a safety measure when they show benefit for detection of bacterial contamination not revealed by previous bacterial testing. The laboratory should follow its own quality control procedures for these uses.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CBER, Office of Device Evaluation (ODE)

Division Sign-Off, Office of Blood Research and Review