April 16, 2018

Immunetics, Inc.
Attention: Ms. Ginger Abraham-Freel
27 Drydock Avenue
Boston, MA 02210-2317

Re: BK170149

Trade/Device Name:	BacTx® Bacterial Detection Kit
Regulation Number:	21 CFR 866.2560
Regulation Name:	Microbial growth monitor
Regulatory Class:	Class I
Product Code:	MZC
Dated:	April 16, 2018
Received:	April 16, 2018

Dear Ms. Abraham-Freel:

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 801); 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

510(k) Number: BK170149

Device Name: BacTx® Bacterial Detection Kits for Platelets

Indications for Use:

The Immunetics BacTx® Bacterial Detection Kit for detection of bacteria in platelets is a rapid, qualitative, colorimetric, quality control test for the detection of aerobic and anaerobic, Gram-positive and Gram-negative bacteria in:

-Leukocyte Reduced Apheresis Platelet units (LRAP) (Apheresis Platelets Leukocytes Reduced) as a quality control test following testing with a growth based bacterial detection device cleared by the FDA for quality control testing of leukocyte reduced apheresis platelets and;

-Pools of up to six (6) units of Leukocyte Reduced Whole Blood-Derived Platelets (Platelets, Leukocytes Reduced) that are pooled within four (4) hours of transfusion.

-Pre-storage pools of up to six (6) units of Leukocyte Reduced Whole Blood Derived Platelets (LR-WBDP) as a quality control test.

Prescription Use (Part 21 CFR 801 Subpart D)	X	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 Blood Research and Review

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Division Sign-Off, Office of Blood Research and Review