DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Haemonetics Manufacturing, Inc.
Attention: Ms. Elizabeth Mason
1630 Industrial Park Street
Covina, CA 91722

Re: BK160027

Trade/Device Name:	Acrodose™ PL System
Regulation Name:	Container, Empty, For Collection & Processing of Blood & Blood Components
Regulatory Class:	Class II
Product Code:	KSR
Dated:	May 2, 2016
Received:	May 3, 2016

Dear Ms. Mason:

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 807); labeling (21 CFR 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 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Basil Golding, MD
Director
Division of Hematology Research and Review
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosure:
Indications For Use

Indications for Use

510(k) Number: BK160027

Device Name: Acrodose™ PL System

Indications For Use:

The Acrodose™ PL System is indicated for pooling of ABO identical, leukocyte-reduced, whole-blood-derived platelet concentrates and subsequent storage for up to 5 days after blood collection when coupled with a device cleared by FDA for detection of bacterial contamination in pooled leukoreduced whole-blood-derived platelets.

The Acrodose™ PL System should be used with whole-blood-derived platelet concentrates collected in CP2D anticoagulant and leukoreduced using the Leukotrap® RC PL or Leukotrap® PL Filtration Systems. Each CLX® HP extended storage bag can store 2.2 – 5.8 x 10^{11} platelets, from 4 to 6 platelet concentrates, at a platelet concentration of ≤ 2.3 x 10^{6}/µL, in a volume of 180 – 420 mL.

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 Blood Research and Review

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Division Sign-Off
Office of Blood Research and Review