



Food and Drug Administration  
1401 Rockville Pike  
Rockville, MD 20852-1448

APR 14 2005

Haemonetics Corporation  
Attention: John Sokolowski  
400 Wood Road  
Braintree, Massachusetts 02184

Re: BK050006  
Product: ACP 215 Glycerolization/Deglycerolization System  
Date Received: 02-FEB-05  
Classification: II  
Device Code: KSW

Dear Mr. Sokolowski:

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. 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 has been classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

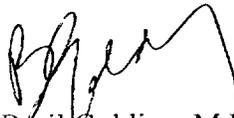
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

2-John Sokolowski

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice on promotional labeling and advertisement for your device, please contact our Advertising and Promotional Labeling Staff (HFM-602) at (301) 827-3028. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 835-4709 or (301) 827-1800 or at its Internet address:  
<http://www.fda.gov/cber/smlbus.htm>.

Sincerely yours,



Basil Golding, M.D.

Director

Division of Hematology

Office of Blood Research and Review

Center for Biologics

Evaluation and Research