DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Office of the Commissioner
5600 Fishers Lane (HF-7)
Room 14-105
Rockville, MD 20857

January 13, 1997

Christina L. Lowell
Vice President, CFO
Biometric Imaging, Inc.
1025 Terra Bella Ave.
Mountain View, CA 94043

RE: Request for Designation
STELLer™ CD34+ Test Kit used in conjunction with the
IMAGN® 2000 Instrument
Our File: RFD 96.029

Dear Ms. Lowell:

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on November 12, 1996.

The product consists of the STELLer ™ CD34+ Test Kit and the IMAGN® 2000 Instrument (IMAGN). (IMAGN is cleared under a premarket notification (k945756) as part of an assay system [ ]. The product is used to determine the concentration of CD34+ cells in apheresis product and peripheral blood. According to the request, the product will be used in [ ].[1]

Biometric Imaging recommended that primary jurisdiction for the premarket review of the product be assigned to the Center for Biologics Evaluation and Research (CBER). After considering the information in the request, and consulting with appropriate officials in CBER and the Center for Devices and Radiological Health (CDRH), I am in substantial agreement with your recommendation. Therefore, I am designating CBER as the agency component with primary jurisdiction for the premarket review and regulation of the product. The product will be subject to review as a medical device under the 510(k) premarket notification provisions of the Federal Food, Drug, and Cosmetic Act.

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[1] Use of the system in the diagnosis or treatment of individual patients raises different jurisdictional questions that are not addressed in this letter.

The Division of Blood Applications, Office of Blood Research and Review, CBER, will be the reviewing division. The division will consult with review staff in CDRH, as appropriate. For further information, contact Mr. Leonard T. Wilson, Chief, Biologics Device Branch, at 1401 Rockville Pike (HFM-385), Suite 400N, Rockville, MD 20852 or by telephone at 301-827-3524. Please include a copy of this letter in your next submission to CBER.

If you have any questions about this letter, please contact me at 301-827-3390.

Sincerely yours,

Steven H. Unger
Deputy, Office of the Chief Mediator and Ombudsman

cc: Leonard T. Wilson