DEPARTMENT OF HEALTH & HUMAN SERVICES
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: REQ 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
(k045766) 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

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

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 CDRA, 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. Langer
Deputy, Office of the Chief Mediator and Ombudsmen

cc: Leonard T. Wilson