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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Commissioner
5600 Fishers Lane
Room 14-105, HF-7

Food and Drug Administration
Rockville MD 20857

April 22, 1996

Ms. Karen Baker
Manager, Regulatory Affairs
Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, California 95131

Re: Request for Designation
ProCOUNT™ Progenitor Cell Enumeration Kit
Our File: RFD-96-06

Dear Ms. Baker:

The Food and Drug Administration (FDA) has completed its evaluation of the above-referenced request for a product jurisdiction determination, accepted for filing on February 21, 1996.

The ProCOUNT™ Progenitor Cell Enumeration Kit (ProCOUNT™) is described as [ ] *in vitro* diagnostic system. ProCOUNT™ includes [ ]

[ ]

The kit is intended for use as an *in vitro* diagnostic test to characterize [ ] by identifying and enumerating absolute counts (cells/μL) and percentages of CD34+ cells (stem cells) in samples of human peripheral blood, mobilized peripheral blood, and leukapheresis. The ProCount™ [ ]

[ ]

BDIS recommended that the primary responsibility for the premarket review and regulation for ProCOUNT™ be assigned to the Center for Biologics Evaluation and Research (CBER). BDIS also asked that the Agency confirm that the product would be eligible for review as a medical device under the section 510(k) premarket notification provisions of the Federal Food, Drug, and Cosmetic Act (the Act). 21 U.S.C. § 360(k).

After considering the information you have submitted, and consulting with staff in CBER and the Center for Devices and Radiological Health (CDRH), I am in substantial agreement with BDIS's recommendation. Accordingly, CBER is designated as the agency component with primary jurisdiction for the premarket review and regulation of the product.

ProCOUNT™ will be subject to review under the medical device provisions of the Act. 21 U.S.C. 360 *et seq.* Eligibility for review under the premarket notification provisions should be discussed with the CBER review division. Any clinical investigations of the product should be conducted in accordance with the investigational device exemption (IDE) requirements in 21 C.F.R. Part 812.

The Office of Blood Research and Review (OBRR) in CBER will be the primary review office, and will be responsible for coordinating the review with CBER's Office of Therapeutics Research and Review (OTRR). OBRR also will consult with review team members in CDRH as necessary. Questions about submission requirements should be directed to Ms. Mary Gustafson, Director, Division of Blood Applications, at OBRR CBER (HFM-370), 1401 Rockville Pike, Rockville, MD 20852-1448, or at 301-827-3524. Please submit a copy of this designation letter in your initial submission to CBER.

Please note that this designation decision applies only to the use of the ProCOUNT™ as an analytical method to characterize [ ] by providing an absolute count or percentage of CD34+ cells. If BDIS proposes to pursue premarket review of this product for other uses, *e.g.*, diagnosing disease or monitoring treatment, BDIS should discuss the appropriate regulatory pathway with this office early in the development process.

If you have any questions regarding this matter, please contact Ms. Andrea Chamblee, of this office, at 301-827-3390.

Sincerely yours,

Amanda B Pedersen

Amanda B. Pedersen
Chief Mediator and Ombudsman