DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

OCT 13 1998

Mr. William Duffell
COBE BCT
1201 Oak Street
Lakewood, CO 80215

Re: BK970005
Product: Focussed System
Date Received: 12-MAR-97
Classification: II

Dear Mr. Duffell:

We have reviewed your Traditional 510(k) notification of intent to market the device referenced above and have determined that the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act that include requirements for registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device has been classified into either class II (Special Controls) or class III (Premarket Approval), (see above), it may be subject to the above and additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note that this response to your Premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

This letter will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of

your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on promotional labeling and advertisement for your device, please contact our Advertising and Promotional Labeling Staff (HFM-202) at (301) 827-3028.

Sincerely,

Jay S Epstein, M.D.
Director
Office of Blood Research and Review
Center for Biologics
Evaluation and Research

PREPARED BY: HFM-385: BPoindexter/MNorthern 10/8/98
(BK970005.SE)