P/M c Keever HFM-17

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

September 5, 2001

Steven Binion, Ph.D.
Baxter Healthcare Corporation
Route 120 and Wilson Road
Round Lake, IL 60073

Re: Reclassification Order:
[Docket No. 96P-0484]
[Reclassification of Autopheresis-C System from Class III to Class II]

Dear Dr. Binion:

The Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA) has completed its review of your petition for reclassification of the Autopheresis-C that is intended for use in the routine collection of blood and blood components. FDA concludes that this device and substantially equivalent devices of this generic type, should be reclassified from class III into class II. This order, therefore, reclassifies the Autopheresis-C, and substantially equivalent devices of this generic type into class II, under the generic name Automated Blood Cell Separators, effective immediately. This order also identifies the special control applicable to the device as the filing of an annual report by the manufacturer with the FDA on the anniversary date of the reclassification for three consecutive years. You do not need a 510(k) premarket notification, and you may immediately begin commercial distribution of the reclassified device, the Autopheresis-C for the routine collection of blood and blood components.

FDA identifies this generic type of device, the subject of this reclassification, as follows:

An Automated Blood Cell Separator is a device intended for use in the routine collection of blood and blood components.

The Autopheresis-C is an automated plasmapheresis system. It utilizes a spinning membrane separation device to achieve rapid and gentle separation by filtration of whole blood into concentrated cellular components for reinfusion and into plasma for collection.

The instrument uses a system of pumps and sensors controlled by a microprocessor and it incorporates a variety of safety and alarm system functions. It uses a fully automated processing program to collect a preset volume of plasma from a donor. Plasma collection in the Autopheresis-C System involves sequential phases of collection of plasma and reinfusion of the residual red blood cell concentrate back to the donor.

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device

96P-0484 PAV 1

Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) the device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act (21 U.S.C. 360c(f)(2)), as amended by the FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

As you know, on December 11, 1996, FDA filed your petition requesting reclassification of the Autopheresis-C from class III into class II. The petition was submitted under section 513(f)(2) of the act, now section 513(f)(3) of the act, as amended by the FDAMA, and 21 CFR 860.134 of the agency's regulations. In accordance with section 513(f)(1) of the act, the Autopheresis-C was automatically classified into class III because the Autopheresis-C was not within a type of device, which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and had not been found substantially equivalent to a device placed in commercial distribution after May 28, 1976, which was subsequently reclassified into class II or class I. In order to reclassify the Autopheresis-C intended for use in the routine collection of blood and blood components into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of safety and effectiveness of the device for its intended use.

Pursuant to 21 CFR 860.125 and 860.134, FDA consulted with the Blood Products Advisory Panel (the Panel). The Panel UNANIMOUSLY recommended that the Autopheresis-C for use in the routine collection of blood and blood components be reclassified from class III into class II because the Panel believes that the Special Control will provide reasonable assurance of the safety and effectiveness of the device. This recommendation was based on the information and data contained in the reclassification petition, and provided by FDA, on information presented during the open public hearing and open committee discussions of the meeting held on September 27, 1996, and on the Panel member's own personal knowledge of, and clinical experience with, the device.

The report and recommendation of the Panel were published in the Federal Register of May 29, 2001, 66 FR No.103 pages 29149-29152, (enclosed)] and interested persons were invited to comment by August 13, 2001. FDA received no comments in response to the notice of panel recommendation.

FDA AGREES with the Panel's recommendation to reclassify the Autopheresis-C from class III into class II with the following identified special control, namely; as the filing of an annual report by the manufacturer with the FDA on the anniversary date of the reclassification for three consecutive years. This decision is based on the administrative record which consists of the reclassification petition, the transcript and minutes of the September 27, 1996 meeting of the Panel, the Panel member's individual data sheets containing their recommendations, and all other

information identified in this letter.

After review of the information submitted in the petition, and consultation with the Panel regarding the reclassification petition, FDA has determined that the Autopheresis-C intended for use in the routine collection of blood and blood components as described and identified herein can be reclassified from class III into class II with the establishment of special control. FDA believes that class II with the SPECIAL control provides a reasonable assurance of the safety and effectiveness of the device.

Risks are listed in section V and the Special Control is in section VIII.

A notice announcing this reclassification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852-1448 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

If you have any questions concerning this reclassification order, please contact Martin E. Northern at (301)827-6124.

Sincerely yours,

for

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

Enclosure

SEP 05 2001

Concurrence Format for CBER Outgoing Correspondence

Application Number [BLA/IND/NDA/IDE/510(k)/PMA] _____

Letter Type: Reclassification of the Baxter'sAutopheresis-C

Cc: P. McKeever HFM-17
D. Zavagno GCF-1
M. Weinstein HFM-330

History: Prepared by M. Northern 8/28/01
Revised by P. McKeever 8/29/01

File Name: My documents Baxter Auto-c Device Reclassification Order

Concurrence box

Office	Name/Signature	Date
HFM	Print Name/Sign Name	Enter Date
HFM-380	NORTHERN / Mark E. Northern	8/29/01
HFM-380	Hedjar / Sayed Hedjar	8/29/01
370	Heinz Lewin	8/30/01
370		8/30/01