

**TELECON**

DATE: 3/15/02, approximately 9:00 am EST

PARTICIPANTS: Paula McKeever, CBER/IOD/RPS

Jeme Wallace  
1-847-270-2717  
Baxter Healthcare Corporation

SUBJECT: Petition for reclassification of the Autopheresis-C System, automatic blood cell separator intended for routine collection of blood and blood components, from a class III to a class II device. (Docket No. 96P-0484/CCP 1)

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**BACKGROUND:** On December 11, 1996, FDA filed a petition submitted by Baxter, requesting that FDA reclassify the automatic blood cell separator, Autopheresis-C system, intended for the routine collection of blood and blood components, from a class III to a class II device. Consistent with the act and the regulations, we referred the petition to the Blood Product Advisory Committee (BPAC) for its recommendation on the requested reclassification. BPAC met on September 27, 1996, and unanimously recommended that the Autopheresis-C System, intended for routine collection of blood and blood components, be reclassified from class III to class II with special controls. On May 29, 2001, we issued a notice of panel recommendation in the Federal Register (66 FR 29149) requesting public comment on the reclassification. No comments were submitted to the docket.

Under 21 CFR 860.134, we sent a written order of approval of the petition to Baxter on September 5, 2001.

**DISCUSSION:** I called Ms. Wallace to ask if Baxter considers the approval order of reclassification dated September 5, 2001, to be a satisfactory response to the petition. She responded that Baxter is satisfied now that the device is reclassified and that FDA has answered the petition. We then both agreed to close the docket.

cc:

96P-0484

MTI