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

DEC 01 1998

Mr. Edward J. Nelson
MEDSEP Corp.
330 Turnbull Canyon Road
City of Industry, CA 91745
USA

Re: BK980027
Product: Transfer/Freezing Bag Set
Date Received: 03-AUG-98
Classification: II

Dear Mr. Nelson:

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the above referenced device has been reviewed by the Center for Biologics Evaluation and Research (CBER). Based upon the information submitted, we are unable to determine that the subject device is substantially equivalent to marketed devices.

Our review indicates that your submission requires the following additional information and clarification:

1. The Diagrams of the Transfer/Freezing Bag Set (Figures 3.1 and 3.2) do not indicate the ____________ nor do they indicate ____________. All of this information should be provided in the complete description of the device.

2. In Section 5, page 5:1, it is stated that the freezing bag component of the Transfer/ Freezing Bag Set has a removable section for thawing an aliquot of the contents. This section of the bag should be clearly indicated in the Figure of the bag and clearly illustrated in the instructions for use. Product integrity data should be provided to assure that the

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
[illegible]	[illegible]	11/23/98	370	[illegible]	11/27/98			
HFM 385	Kochman		385	Brock	12/1/98			
	for W[illegible]	11/23/98						

*U.S. GPO: 1988-216-488

3. In Section 6.2, page 6:1, it is stated that comparative tests of the freezing bags were performed. Please provide further information to indicate:

   a.)

   b.)

   c.)

4. Please clarify whether this device will be used to

5. If a cryopreservative such as dimethylsulfoxide or another solvent is to be used in the freezing bag, please indicate the

6. The Instructions for Use should include a diagram of the Transfer/Freezing Bag Set which clearly labels

7. There are components listed in the Page 7:3, Table 7, titled Used in Proposed Transfer/Freezing bag Set.

   a.) Please identify which component has been cleared and which has been not been cleared by the Agency. Please incorporate the information with relevant NDA or 510(k) number(s) in the table to facilitate review.

   b.) Please provide

X X for all the components which have not been cleared by the Agency.

In view of the above, CBER is placing your notification in abeyance pending receipt of your response to our comments. As such, the required 90 day waiting period from the date of receipt of your 510(k) submission has been interrupted pending receipt of a response. If no response is received within 30 days of receipt of this letter, your notification will be inactivated, thus requiring a new submission of a Premarket Notification and an additional 90 day waiting period prior to marketing.

Sincerely,

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

PREPARED BY: LHarvath,HFM-335: SHwangbo 11/13/98
Revised by: Lwilson/Shwangbo 11/18/98

510(k): BK980027
Manufacturer: MEDSEP Corp.
Product: Transfer/Freezing Bag Set

To: Division of Blood Applications

From: Sukza Hwangbo, HFM-385

Subject: Review of 510(k) Notification

Date: 13-NOV-98

It is my recommendation that the subject 510(k) notification:

_____ (A) is substantially equivalent to marketed devices.

_____ (B) is not substantially equivalent to marketed devices. Requires a premarket approval. See comments below.

__X__ (C) is deficient; requires more data. See attached letter or comments below.

_____

Biomaterial Review Comments:

There are ___ components listed in the page 7:3, Table 7, titled ___ Used in the Proposed Transfer/Freezing bag set. Please convey the following review comments to the firm:

a. Please identify which component has been cleared and which has been not cleared by the Agency. Please incorporate the information with relevant NDA or 510(k) number(s) in the table for an easy review.

b. Please provide biocompatibility data for all the components not cleared by the Agency.

Labeling: ____ Acceptable except as noted.
__X__ Not Reviewed.
____ Revised to include as noted.

Reviewer: Sukza Hwangbo, R.Ph., D.A.B.T. 11/13/98

Division Director: [signature] 12-3-98
Date