K970739

July 8, 1997

**Attachment II.A.**

SMDA Summary of Safety and Effectiveness Information

In compliance with requirements of the Safe Medical Device Act (SMDA) of 1990, the following information is submitted as a summary of safety and effectiveness information for this 510(k) premarket notification:

1. **Predicate Device Identification:** A claim of substantial equivalence of the RMI Hemoconcentrator Preference Pack, or components thereof, is made to the:

   - COBE CV *Personalized* Hemoconcentration Packs, 510(k) number unknown [possibly K823338];
   - COBE CV 3 Liter Waste Bag For Filtrate Collection, preamendment device;
   - COBE CV Hemoconcentrator, K823338;
   - Baxter Bentley HemoCon 1.3, 510(k) number unknown;
   - ALTREX® 140 Hemodialyzer, K945596;
   - RMI Hemoconcentrator, HEM-140, K951344; and
   - RMI Hemoconcentrator Tubing Set with adapters, TS-024, and Ultrafiltrate Waste Bag, WB-001, K961927.

   These devices were marketed prior to May 28, 1976 or have received FDA clearance to market since that date.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. R.D. Hibbert
Director, Clinical and Regulatory Affairs
Research Medical, Inc.
6864 South 300 West
Midvale, Utah 84047

JUL - 8 1997

Re: K970739
RMI Hemoconcentrator Preference Pack
Regulatory Class: III
Product Code: 78 KDI
Dated: February 25, 1997
Received: February 28, 1997

Dear Mr. Hibbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other

general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Robert R Malloy

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: RMI Hemoconcentrator Preference Pack

dications For Use:

The RMI Hemoconcentrator Preference Pack is a medical device convenience pack that is intended to allow RMI customers to specify their preference for one or more of the following devices that will be provided in their hemoconcentrator pack:

- Rinse-Required Hemoconcentrator with tubing set and prime lines, LCH-500-A
- Pre-Rinsed BioFilter™ 140 Hemoconcentrator, HEM-001
- 24 inch Hemoconcentrator Tubing Set, TS-024
- 36 inch Hemoconcentrator Tubing Set, TS-036
- Hemoconcentrator Adapter Set, HEM-001 Adapters
- Hemoconcentrator Waste Bag, WB-001
- BioFilter™ 140 with Adapter Set, HEM-001-A
- BioFilter™ 140 with 24 inch Tubing Set, HEM-024
- BioFilter™ 140 with 36 inch Tubing Set, HEM-036
- BioFilter™ 140 with 24 inch Tubing Set and Waste Bag, HEM-024-B
- BioFilter™ 140 with 36 inch Tubing Set and Waste Bag, HEM-036-B
- Hemoconcentrator Pole Mount, HEM-01H

The hemoconcentrator is intended for relief or mitigation of overhydration in patients undergoing cardiopulmonary bypass procedures and to decrease the concentration of plasma water in blood.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Gelburg

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970739

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use_____

(Optional Format 1-2-96)