AUG 13 1996 K961927

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. Device Classification:

The RMI Hemoconcentrator Tubing Set is a set of tubing, fittings and connectors that is used to interconnect an RMI hemoconcentrator to: 1) a location in an extracorporeal circuit that will sustain blood flows up to 500 ml/min, 2) either a cardiotomy or venous reservoir, and 3) a graduated ultrafiltrate collection container.

The RMI Hemoconcentrator Tubing Set is provided sterile and non-pyrogenic.

Research Medical can find no Code of Federal Regulations (CFR) classification for this type of device. Since the RMI Hemoconcentrator Tubing Set is a set of tubing, fittings and connectors that is used to interconnect an RMI hemoconcentrator to a location in an extracorporeal circuit and either a cardiotomy or venous reservoir, Research Medical believes the RMI Hemoconcentrator Tubing Set is a Class II device that could best be classified under the following CFR classifications:

- §870.4210 Cardiopulmonary bypass vascular catheter, cannula, *or tubing*.
- §870.4210 Cardiopulmonary bypass adaptor, stopcock, manifold, *or fitting*.

2. Predicate Device Identification:

To our knowledge, there are no predicates devices for separately sold hemoconcentrator tubing sets.

3. Class III Summary:

[Not applicable]

4. Biocompatibility Assessment

Biocompatibility testing was performed on whole product extract and/or tubesheet slices of the ethylene oxide (EtO) sterilized RMI Hemoconcentrator Tubing Set (test article) in accordance with FDA's May 1, 1995 memo, FDA MATRIX FOR BIOCOMPATABILITY TESTING, which is based on ISO 10993 Standard, Biological Evaluation of Medical Devices. The reports are summarized as follows:

- The Cytotoxicity Test (MEM Elution Test) was performed. Under conditions of the test, the test article is not cytotoxic.
- The Sensitization Test (Guinea Pig Maximization) was performed. For SCI and OIL Extraction Tests, upon rechallenge none of the test group or negative control animals exhibited scores higher than 1. A response of 1 is not considered to reflect significant sensitization.
- A USP Intracutaneous (Irritation) Test was conducted. Under conditions of the test, the test article met the requirements of the USP Intracutaneous Test.

- The Acute Systemic Toxicity Test (USP Systemic Injection Test) was conducted. Under conditions of the test, the test article met the requirements of the USP Systemic Injection Test.

- The Haemocompatibility (Hemolysis) Test for blood compatibility was conducted. The test article had 0.00% Hemolysis.

5. Summary of Functional / Performance Testing:

Flow vs. Pressure Test:
The five (5) product samples tested delivered flows exceeding 1000 ml/min with line pressure under 70 mmHg.

Overpressure and Leak Testing:
The five (5) unit samples tested demonstrated the product will withstand a pressure ten (10) times greater than the standard operating pressure observed during flow testing.

Mechanical Strength Test:
The five (5) unit samples tested demonstrated a six (6) times minimum acceptable pull force per Q.O.P. #80138