

K960098

MAR 26 1996

**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 Internal Mammary Artery Cannula is made to the:

- DLP I.M.A. Cannula, Code #31001, K# Unknown.

This device was marketed prior to May 28, 1976 or has received FDA clearance to market since that date.

2. **Class III Summary:**

[Not applicable]

3. **Statement of Biocompatibility:**

The RMI Internal Mammary Artery Cannula is composed of a chrome-plated brass female luer hub and 304 stainless steel tubing with smooth bulb tip. These materials are standard materials used in medical needle devices marketed prior to May 28, 1976, and since that date. Biocompatibility of these materials is well established and testing is not repeated for this product.

4. **Comparative Information:**

- Summary of Functionality/Performance Comparison of the RMI Internal Mammary Artery Cannula to the DLP I.M.A. Cannula:

**Test Results**

A comparative performance test of the RMI Internal Mammary Artery Cannula, IMA-001, to the DLP I.M.A. Cannula, I.M.A. 31001, was completed. The purpose of the test was to compare the relative flow rates of the cannulae. Under conditions of the test the data shows that the flowrate of the RMI Internal Mammary Artery Cannula, IMA-001, is approximately 25% greater than the DLP I.M.A. Cannula, I.M.A. 31001. Since the flowrate through a cannula indicated for flushing the internal mammary artery with a vasodilator is only an issue if the pressure needed to create the desired flow is too high, it may be concluded that in terms of flow rates, the RMI Internal Mammary Artery Cannula, IMA-001, is substantially equivalent to the DLP I.M.A. Cannula, I.M.A. 31001.

Comparison of Specifications

<b>Characteristic</b>	<b>RMI Internal Mammary Cannula</b>	<b>DLP I.M.A. Cannula</b>
Model	RMI IMA-001	DLP I.M.A. 31001
Female Luer Hub	Chrome-Plated Brass	Plastic
Tubing	26 gauge Stainless Steel	26 gauge Stainless Steel
Tip	1mm Smooth Bulb Tip	1mm Smooth Bulb Tip
Sterilization	EtO	Unknown