

FEB 19 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. **Product:** RMI Dual Fluid Irrigating Syringe

Manufactured by: Research Medical, Inc.  
6864 South 300 West  
Midvale, UT 84047

Phone: (801) 562-0200  
FAX: (801) 562-1122

2. **Description:** The RMI Dual Fluid Irrigating Syringe consists of two Becton Dickinson 10cc syringes pre-assembled in a PVC holster. The dual lumen applicator tip of the Dual Fluid Irrigating Syringe consists of two separate lines of tecoflex tubing that form a 'Y' connection, then remain parallel to deliver two separate solutions or fluids simultaneously onto the surgical site. A three-way stopcock is connected to each syringe to accommodate attachable 36" fluid transfer sets used to draw prescribed solutions or fluids into each syringe. The plunger ends of the 10cc syringes are coupled together with an LDPE yoke.

The RMI Dual Fluid Irrigating Syringe is ethylene oxide (EtO) sterilized and is sold as a disposable, single use, non-pyrogenic device.

3. **Component Materials:** The RMI Dual Fluid Irrigating Syringe is composed of the following fluid contacting components and materials:

<u>Component</u>	<u>Materials</u>
(2) 10cc SLP LL BD#301030 syringes	Standard Becton Dickinson
(2) Three-way stopcocks	Polycarbonate
(2) Parallel fluid pathway lines	Tecoflex tubing
(2) Gish Fluid Transfer Set, CPVMF36S	PVC tubing, PVC female luer-lock, polycarbonate male luer-lock, and ABS end caps

4. **Predicate Device Identification:** A claim of substantial equivalence of the RMI Dual Fluid Irrigating Syringe is made to the following predicate devices:

- Micromedics, Inc. Surgical Sealant Dispenser (SSD); 510(k) Number K881020. [Also marketed as the Micromedics Fibrijet Delivery System]

Marketed by : Micromedics, Inc.  
1285 Corporate Center Drive #150  
Eagan, Minnesota 55121  
Phone: (612) 452-1977  
Fax: (612) 452-1787

- Duoflo™ Dispenser; 510(k) Number K872565.

Marketed by : Hemaedics, Inc.  
2649 Seahorn Drive  
Malibu, CA 90265  
Phone: (213) 454-4757

## 5. Summary of Biocompatibility:

- A Primary Skin Irritation Evaluation was conducted. Under conditions of the test, the Test Article extract did not produce a skin irritation and passed the CFR primary skin irritation.
- The Guinea Pig Maximization (Magnusson/Kligman Method) was performed. Under conditions of the test, the Test Article, extracted in normal saline, was a class I (weak) sensitizer in guinea pigs using the Magnusson/Kligman Guinea Pig Maximization test. A response of 1 is not considered to reflect significant sensitization
- The Cytotoxicity Test (MEM Elution Test) was performed. Under conditions of the test, the Test Article is not cytotoxic.
- The Cytotoxicity Test (Agar Overlay Test) was performed. Under conditions of the test, the Test Article is not cytotoxic. All components met the USP guidelines with a grade of 2 or lower.
- The Acute Systemic Toxicity Test (USP Systemic Toxicity Evaluation) was conducted. Under conditions of the test, there was no reaction of the mice to the Test Article when observed at intervals for a period of 72 hours following treatment.
- The Hemocompatibility (Hemolysis Test) for blood compatibility was conducted. Under conditions of the test, the Test Article had 0.20% Hemolysis. Experience with this test on a wide range of samples indicates that less than 5% hemolysis should not be considered significant. The 5% level is based on the reproducibility and ruggedness of the assay.
- The Hemocompatibility (Thrombogenicity Test) was performed to quantitate the thrombogenic potential of the Test Article. Under conditions of the test, the average clotting time for the negative control sample was 137.3 seconds. The average clotting time for the Test Article was 129.5 seconds. Summarized, the test sample did demonstrate shortened clotting time (thrombogenic risk was detected.)
- The Material Mediated Pyrogenicity Test (Limulus Test) was performed. Under conditions of the test, the Test Article is not pyrogenic.
- USP muscle implantation tests (Seven Day Muscle Implant Evaluation) were performed on various components of the Test Article. Under conditions of the test, all tested components of the Test Article met the requirements of the 7 day USP muscle implant test.
- The Salmonella Typhimurium Reverse Mutation Assay (AMES Test) was performed. Under conditions of the test, extract of the Test Article tested against five strains did not meet the criteria for a potential mutagen.

**6. Functional/Performance and Comparative Information**

A. Summary of Functional Testing of the RMI Dual Fluid Irrigating Syringe:

Table of Tests and Results

<u>Parameter</u>	<u>Results</u>
DFIS Leak Test @ 2 PSI (13 units):	Passed
DFIS Flow Test @ 1.0 CFH (13 units)	Passed
DFIS Pull Test -- 5 lbs. minimum	
Left stopcock / tubing (13 units)	All pulled to 17 lbs. or more.
Right stopcock / tubing (13 units)	All pulled to 17 lbs. or more.
Gish Fluid Transfer Set, CPVMF36S	Meets all IQA acceptance criteria

B. Summary of Performance Testing of the RMI Dual Fluid Irrigating Syringe:

Performance [functionality] testing shows that the RMI Dual Fluid Irrigating Syringe (DFIS) is substantially equivalent in performance to: (1) two single 10cc syringes, one syringe held in each hand; and (2) two 10cc syringes taped together held in one hand. The testing showed that the DFIS not only delivers fluids simultaneously, but in an equal 1:1 ratio.

C. Summary of Comparison of RMI Dual Fluid Irrigating Syringe (DFIS) to Micromedics Fibrijet Delivery System:

Table of Comparison

Characteristic	Research Medical, Inc.	Micromedics
Model	DFIS	SA-4310
Syringe Volume	(2) 10cc	(2) 10cc
Syringe Assembly	Pre-assembled in PVC holster	Syringes clipped into assembly
Syringe pistons	yoke-coupled	Syringe pistons yoke-coupled
Fluid Applicator Tip	Pre-assembled on DFIS	SA-3615 selected representative
	<u>Characteristics</u>	<u>Characteristics</u>
	Dual lumen tip configuration	Dual lumen tip configuration
	Parallel .039 ID Tecoflex tubing	20ga. malleable cannula
Sterilization	ETO	Unknown