

K961717

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**Summary of Safety and Effectiveness**  
**NMI RETROGRADE CARDIOPLEGIA CANNULA - RCCS**

**I. General Information**

- A. Generic Name: Retrograde Cardioplegia Cannula
- B. Trade Name of Device: NMI Retrograde Cardioplegia Cannula-RCCS
- C. Applicant's Name and Address: Naltiac Medical, Inc.  
17194 Preston Rd, Suite 123-206  
Dallas, TX 75248
- D. Pre-market Notification Number: Not yet assigned

**II. Indications For Use**

The NMI Retrograde Cardioplegia Cannulae-RCCS are intended for use in perfusing blood or Cardioplegia solutions via the coronary sinus during cardiopulmonary surgery.

**III. Device Description**

The NMI Retrograde Cardioplegia Cannulae are fabricated with polyvinyl chloride bodies (PVC) and polyurethane balloon cuffs, polycarbonate/polyethylene stopcocks, polypropylene clamps, PVC female luer connectors, and stainless steel guidewires. The features of the device include: self-inflating cuff, pressure monitoring port with 3-way stopcock on lumen extension, suture ring, and 14 French size. The cannulae are placed in the coronary sinus in order to infuse cardioplegia in a retrograde fashion to the myocardium. This practice both arrests the heart and preserves metabolic function during surgery.

**IV. Device Classification: Class II**

**V. Safety and Effectiveness**

Substantial Equivalence: This device has been shown to be substantially equivalent to the Research Medical, Inc. Retrograde Cardioplegia Cannula # K880103

**VI. Other Safety and Effectiveness Data:**

Materials: Fluid contact materials of construction comply with Tripartite Biocompatibility Guidance for external devices, blood path direct, short term use

Sterilization: Validated 100% Ethylene Oxide sterilization cycle (Overkill Method) SAL  $10^{-6}$

Pyrogenicity: Non-Pyrogenic per USP Pyrogen test (LAL)

**Functional Testing**

Pressure Drop / Saline

NMI cannulae average pressure drops range at flow rates between 100 and 500 ml/min = 11 to 76 mmHg at 4°C

RMI cannulae average pressure drops range at flow rates between 100 and 500 ml/min = 7 to 97 mmHg at 4°C

Pressure Drop / Saline

NMI cannulae average pressure drops range at flow rates between 100 and 500 ml/min = 6 to 60 mmHg at 40°C

RMI cannulae average pressure drops range at flow rates between 100 and 500 ml/min = 6 to 97 mmHg at 40°C

Pressure Drop / Bovine Blood (@25% Hematocrit)

NMI cannulae average pressure drops range at flow rates between 100 and 500 ml/min = 22 to 121 mmHg at 4°C

RMI cannulae average pressure drops range at flow rates between 100 and 500 ml/min = 14 to 127 mmHg at 4°C

NMI cannulae average pressure drops range at flow rates between 100 and 500 ml/min = 11 to 77 mmHg at 40°C

RMI cannulae average pressure drops range at flow rates between 100 and 500 ml/min = 12 to 91 mmHg at 40°C

Pressure Monitoring Port:

NMI cannulae 0.5 to 0.9 mmHg for downstream pressures of 10 to 80 mmHg

RMI cannulae 0.6 to 0.9 mmHg for downstream pressures of 10 to 80 mmHg

Balloon Burst:

Greater than 130 mmHg

Guide Collapse:

Less than predicate device

Balloon Device:

Greater than predicate device

Leak Test Requirements:

No leaks at 10 psi air on NMI Device @ 4°C and 40°C

Tubing Bond Strength:

Exceeds 0.4 lb tensile strength @ 4°C and 40°C

Luer Connections:

Meets ANSI/HIMA MD70.1-1983 for Medical Materials Luer Taper Fittings

Package Integrity:

Tyvek/Mylar passed burst test in accordance with ASTM F1140-88

Shipping & Distribution Testing:

Passed Distribution Simulation Test per ASTM 40169 Standard

Accelerated Aging

One year - No effects on performance