

K 9453945

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SUMMARY OF SAFETY AND EFFECTIVENESS

1. **INDICATIONS:** The indications or intended use for the DLP Elongated and Treaded Cuff Retrograde Coronary Sinus Perfusion (RCSP) cannula are the same as the DLP, Research Medical and Sarns 3M marketed RCSP cannula. The cannula are intended for use in perfusing cardioplegia solutions retrograde through the coronary sinus.
2. **DESIGN:** The design of the DLP Elongated and Treaded Cuff RCSP cannula is similar to predicate products. Size and shape contain minor differences. Technological characteristics are equivalent. Cuff length and texture differences do not affect flow characteristics.
3. **MATERIALS:** The materials used for the cuffs and cannula body are silicone which is same as that for DLP and SARNs 3M marketed RCSP devices. Materials have been tested to be biocompatibility acceptable.
4. **SAFETY & EFFICACY:** No difference in Safety and Efficacy. Since materials, indications and technology are the same, no new issues of Safety and Efficacy of the device are introduced.
5. **DIFFERENCES:** The differences are minor and nonsignificant differences.

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