

K963248

## Summary of Safety and Effectiveness

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Ref : Flow Directed Thermodilution / Infusion Balloon Catheter  
By J-Lloyd Medical, Inc.

The effectiveness of the J-Lloyd catheter is equivalent to the Nova Medical Specialties, Inc. design, in that they both perform their designed functions, which is to provide a means to obtain right heart pressure readings from various parts of the right heart and cardiac output. Test indicate that the materials used in both catheters exceed the strength required. The bond joints will withstand tensile pressures in excess of that required for safety and effectiveness. Tests for other design characteristics such as balloon burst strength, and injection rate showed little of significance. As with any invasive procedure, there are certain inherent hazards. These hazards have been identified in the instruction sheet under the titles of Precautions and Warnings. it is important that the physicians be aware of the basic principles involved prior to using these devices in their varied application.

Engineering tests of the design indicate the effectiveness and safety of these devices present an acceptable level of safety when properly used by a trained physician.