

1-14-97

K964154

## Section 2 - Summary & Certification

### A. 510(k) Summary

Trade Name: *Segue*<sup>TM</sup> Infusion Catheter

Classification Name: Continuous Flush Catheter

Classification: Class II

Submitted By: Interventional Innovations Corporation  
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Predicate Device: *Segue*<sup>TM</sup> Infusion Catheter  
FasTRACKER<sup>®</sup> Infusion Catheter (Target Therapeutics)

### Device Description

The Segue Infusion Catheter is a single lumen, over-the-wire device designed to locally deliver solutions into the peripheral and coronary vasculature.

### Intended Use

The Segue Infusion Catheter is indicated for the delivery of solutions into the peripheral and coronary vasculature.

### Testing

Physical testing of the product under simulated conditions included: dimensional inspection, deployment and recoil verification, marker band attachment, infusion flow rate, internal pressurization, bond strength, flexural fatigue strength, radial force and trackability. All testing results were within product engineering and marketing specifications.

Biocompatibility testing was performed on the sterile materials used in the construction of this infusion catheter. All materials passed the biocompatibility testing and are suitable for this application.

Animal studies were conducted to assess the effects of the device on the vessel wall as well as thrombogenicity effects of the device. There were no adverse results reported.

### Summary of Substantial Equivalence

The Segue Infusion Catheter is constructed of the same or substantially equivalent materials as found in the predicate device. The sizes and configurations available are comparable as is the packaging methods and materials. The clinical indications for use are substantially equivalent to those of the predicate device. Because of the similarities in materials, construction, indications for use, packaging and testing results, this product does not raise any new safety or effectiveness issues.