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510(k) Summary of Safety and Effectiveness

CENTERMARK\* Catheter Introducer Sheath  
With PROTECTIV\* 2000 Needle Safety System

The CENTERMARK \* Catheter Introducer Sheath with PROTECTIV\* 2000 Needle Safety System is designed for percutaneous access for the introduction of catheters and guidewires. The PROTECTIV\* 2000 Needle Safety System is designed to reduce needle sticks injuries.

The introducer sheath portion of the system is the same product that is currently marketed by JJMI. The Safety system has passed all tests for safety and effectiveness (i.e. biocompatibility, sterility and system performance).