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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Pursuant to Section 12, Safe Medical Devices Act of 1990)

1. The trade or proprietary name of the device is the Medtronic® MUSTANG™ Steerable Guide Wire. The common or classification name is Coronary Guidewire.

2. The Medtronic® MUSTANG™ Steerable Guide Wire is for use in introducing and placing interventional catheters during percutaneous transluminal coronary angioplasty (PTCA) and/or percutaneous transluminal angioplasty (PTA).

3. The Medtronic® MUSTANG™ Steerable Guide Wire is a guide wire having a maximum diameter of 0.014" (0.36 mm). The proximal shaft is coated with a polymer and the distal 33 cm contains a lubricious coating. The distal segment of the wire contains a spring which is radiopaque. The MUSTANG™ is provided sterile, and is intended for one procedure use only (disposable).

4. *In vitro* testing included tensile strength, torque strength, torqueability, tip flexibility, coating adherence/integrity and catheter compatibility. Testing was performed to assess the biocompatibility of the device.

5. Test results verified that the MUSTANG™ meets all of the applicable specifications and is deemed adequate for the intended use. The MUSTANG™ is considered to be substantially equivalent to the following devices:

   ACS® Hi Torque Floppy II® Guide Wire

   Scimed® Sceptor™ Floppy Guide Wire