

K961107

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**II. SUMMARY OF SAFETY AND EFFECTIVENESS**

**Applicant Name & Address:** B. Braun Medical Inc., Cardiovascular Division  
824 Twelfth Avenue  
Bethlehem, Pa 18018

**Contact:** Mark Alsberge, Regulatory Affairs Manager

**Date Prepared:** June 21, 1996

**Common or Usual Name:** B. Braun Guidewires

**Device Classification Name:** Wire, Guide, Catheter

**Substantial Equivalence:** ACS Guidewires-- K852123, K852354 , K854830, K861574, K861765, K862360, K864585, K872220, K874202, K874776, K881787, K881897, K884262, K884895, K902755, K905502, K913328, K913631, K915723, K925381, K934602, K942066 / or K950156  
Target Guidewires--K884198, K922912 / or K914032  
USCI Guidewires--K924009 / or K933466

**Guidewire Device Description:** The Braun Guidewire is a steerable, shapeable guidewire. The guidewire is available in a variety of diameters, stiffnesses, and lengths. Certain sizes are extendible to exchange lengths.

**Extendible guidewires have an attachment at the proximal end of the guidewire which is adapted to receive a Braun Guidewire extension wire. Extending the guidewire enables exchange of intravascular devices while maintaining distal guidewire position. The extension is removable and permits the guidewire to be returned to its original length and functionality.**

**Extension Wire Device Description:** The Braun Guidewire extension wire is available in sizes compatible with Braun Guidewire extendible guidewires. The distal end of the extension is adapted to engage the proximal end of the guidewire enabling exchange of intravascular devices while maintaining distal guidewire position. The extension is removable and permits the guidewire to be returned to its original length and functionality.

**Statement of Intended Use:**

**The Braun Guidewire is intended to fit inside a catheter for the purpose of directing the catheter through a blood vessel. These catheters may be used for PTCA and PTA procedures. These guidewires are not intended for use for cerebral, reproductive, or neurological procedures.**