

## II. SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant Name & Address: B. Braun Medical Inc., 824 Twelfth Avenue  
Bethlehem, PA 18018 (610)691-5400

K961745

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Common or Usual Name: Braun Percutaneous Introducer Set

Device Classification Name: Catheter Introducers & vessel dilators

SEP 17 1996

### Substantial Equivalence:

K810460	Burron Percutaneous Introducer Set	B. Braun Medical, Inc.
K894446	Angeion Hemostasis Introducer Set	B. Braun Medical, Inc.
K894343 and/or K884494	Venous Introducer	Daig
K771982 and/or K770561	"888" Percutaneous Catheter Introducer	USCI
K780126	PCI Kit	Argon
K850820	Arterial/Venous Percutaneous Catheter Introducer	Universal Medical Instrument(UMI)
K932733	Valveless/Portless Sheath Introducer	Cordis

### Device Description:

Braun Percutaneous Introducer Kits consist of an introducer sheath packaged with a corresponding dilator. A guidewire and introducer needle may also be packaged with the sheath and dilator.

### Statement of Intended Use:

The Braun Percutaneous Introducer Kits are designed to facilitate percutaneous introduction of devices into the vasculature.

### Summary/Comparison of Technological Characteristics:

	Braun PCI	K810460	K894446	Daig	USCI	Argon	UMI	Cordis
Fr sizes	3 - 9	6-8	4-15	4 - 9	4 - 9	4 - 9	4 - 8	6 - 8
Lengths	7 - 24 cm	not specified in 510(k)	12 - 24 cm	8.5 - 12 cm	8 - 12 cm	unknown	14 cm	11 cm
Mats	Teflon FEP or HDPE sheath with HDPE dilator	Teflon® FEP sheath & dilator	Teflon® FEP sheath and HDPE dilator	unknown - "proprietary materials"	Teflon	unknown	white teflonsheath with polyethylene dilator	unknown
Sideport	no	yes	yes	no	no	no	no	no
Gasket	no	no	yes	no	no	no	no	no
Use	percutaneous introduction of devices into the vasculature	percutaneous introduction of devices into the vasculature.	percutaneous introduction of catheters into the vasculature while minimizing the backflow of blood.	Designed for introduction of electrophysiology and other catheters into the venous system	percutaneous introduction of catheters into the vasculature (either venous or arterial)	percutaneous introduction of balloon catheters, closed end catheters and temporary pacing leads into the vasculature.	percutaneous introduction of catheters into the vasculature (either venous or arterial)	percutaneous introduction of catheters into the vasculature