

II. SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant Name & Address: B. Braun Medical Inc., Cardiovascular Division, 13000 Hwy 55
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Common or Usual Name: Catheter introducer and Vessel dilator for percutaneous catheterization

Device Classification Name:

Introducer: 21 CFR Reference- 870.1340, Class II Panel- 74 DYB

Dilator: 21 CFR Reference- 870.1310, Class II, Panel- 74 DRE

Substantial Equivalence:

510(k) #	Product	Manufacturer
K894446	Angeion Hemostasis Valve Introducer Kit	B. Braun Cardiovascular - MN
K931743	Burrton Cardiovascular Angestat	B. Braun Cardiovascular - MN
K871153	ANGETEAR Tear-away Introducer Kits	B. Braun Cardiovascular - MN
K930057	Fluoro-tip Hemostasis Introducer Set	B. Braun Cardiovascular - MN
K945396	Fluoro-tip Hemostasis Introducer Set	B. Braun Cardiovascular - MN

Device Description:

16 & 18 french versions of the Braun Hemostasis Introducer with silicone gasket, in lengths of 10 - 40 cm.

Statement of Intended Use:

For percutaneous introduction of catheters into the vasculature while preventing the backflow of blood.

Summary/Comparison of Technological Characteristics:

Characteristic	Braun Hemostasis Introducers	K894446 Hemostasis Introducer	K931743 Angestat	K871153 ANGETEAR
A) Labeling/Pkg				
Labels & IFUs	See Attachment B	All Braun Hemostasis Introducer Label formats are identical	All Braun Hemostasis Introducer Label formats are identical	same information provided on pouch and box labels as on hemostasis labels
Expiration Dating	2 years	2 years	2 years	4 years
Pyrogen Free	Yes	Yes	Yes	Yes
Packaging	Tyvek/Polymylar pouch	Tyvek/Polymylar pouch	Tyvek/Polymylar pouch	Tray w/ tyvek lid w/in a tyvek/polymylar pouch
B) Intended Use	percutaneous introduction of catheters into the vasculature while minimizing the backflow of blood	percutaneous introduction of catheters into the vasculature while minimizing the backflow of blood	percutaneous introduction of catheters into the vasculature while minimizing the backflow of blood	percutaneous introduction of catheters into the vasculature
C) Physical Char.				
Available french sizes	4-18 french	5-14 french	4-15 french	4-16 french
Lengths	10-40 cm	12-24 cm	15-32 cm	16-30 cm
gasket material	silicone	Natural rubber	silicone	none
sheath material	FEP with BaSO ₄	FEP teflon with BaSO ₄	FEP with BaSO ₄	polyethylene with bismuth subcarbonate
dilator material	high density polyethylene with bismuth subcarbonate	polyethylene with bismuth subcarbonate	polyethylene with bismuth subcarbonate	FEP with BaSO ₄ or polyethylene with bismuth subcarbonate
D) Anatomical Sites	vasculature	vasculature	vasculature	vasculature

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