

**B. Braun Safeflow**

Summary of Biocompatibility Test Results ISO 10993-1 Standard Testing Procedures			
Test performed	Interpretation	510(k)	Results
Cytotoxicity	The test article is considered non-cytotoxic	K002689	Pass
Acute Systemic Toxicity	The test article extracts would not be considered systemically toxic	K002689	Pass
Acute Intracutaneous Reactivity	No evidence of significant irritation or toxicity from the extracts injected intracutaneously into rabbits	K002689	Pass
Hemolysis (direct contact and chemical)	The test article was determined to be non-hemolytic (less than 5%)	K002689	Pass
Pyrogen Study – Material Mediated	The test article extract was judged as non-pyrogenic	K002689	Pass
Guinea Pig Maximization	The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig	K002689	Pass

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*Safeflow is distributed by B. Braun Melsungen AG*

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