

**K912172 SAFEWEDGE(TM) RELIEF VALVE DEVICE**Sep 27, 1991  
134 days to decisionK912172 · Product code: **KRB** · CardiovascularSource: <https://www.510kdatabase.net/k912172/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Probe, Thermodilution (KRB)
Date received	May 16, 1991
Decision date	Sep 27, 1991
Days to decision	134 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sunscope Intl., Inc.</b>
Location	Westlake Village, CA, US
Contact	KEITH CHAN
510(k) history	7 submissions · 7 cleared · 1991-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912172/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026