

**K972777 TEMPORARY OCCLUSION BALLOON SYSTEM**Mar 11, 1998  
229 days to decisionK972777 · Product code: **MJN** · CardiovascularSource: <https://www.510kdatabase.net/k972777/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Jul 25, 1997
Decision date	Mar 11, 1998
Days to decision	229 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Percu Surge, Inc.</b>
Location	Sunnyvale, CA, US
Contact	EDWARD J SINCLAIR
510(k) history	2 submissions · 1 cleared · 1998-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972777/> 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 July 3, 2026