

**K861428 SUCTION CONTROL VALVE (NONADJUSTABLE)  
CAT.RLV-2100**Jun 26, 1986  
71 days to decisionK861428 · Product code: **DWD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k861428/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suction Control, Intracardiac, Cardiopulmonary Bypass (DWD)
Date received	Apr 16, 1986
Decision date	Jun 26, 1986
Days to decision	71 days
Third-party review	No

**APPLICANT**

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Company	<b>American Omni Medical, Inc.</b>
Location	Costa Mesa, CA, US
Contact	GEORGE G SIPOSS
510(k) history	20 submissions · 20 cleared · 1985-1993

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k861428/> 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 May 27, 2026