

**K080472 SEDAT MYSHELL LITE**Apr 23, 2008  
62 days to decisionK080472 · Product code: **DTL** · Cardiovascular  
Source: <https://www.510kdatabase.net/k080472/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Feb 21, 2008
Decision date	Apr 23, 2008
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sedat</b>
Location	San Diego, CA, US
Contact	LAETITIA COUSIN
510(k) history	3 submissions · 3 cleared · 2006-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080472/> 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 24, 2026