

**K040498 MYSHELL**Jul 2, 2004  
127 days to decisionK040498 · Product code: **DTL** · Cardiovascular  
Source: <https://www.510kdatabase.net/k040498/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Feb 26, 2004
Decision date	Jul 2, 2004
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sedat S.A.</b>
Location	Charlestown, MA, US
Contact	PETER C WOOD
510(k) history	2 submissions · 2 cleared · 2004-2005

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