

**K052381 GUARDIAN HEMOSTASIS VALVE WITH GUIDEWIRE INTRODUCER**Nov 21, 2005  
83 days to decisionK052381 · Product code: DTL · Cardiovascular  
Source: <https://www.510kdatabase.net/k052381/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Aug 30, 2005
Decision date	Nov 21, 2005
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zerusa Limited</b>
Location	Galway, IE
Contact	OONAGH SWEENEY
510(k) history	4 submissions · 4 cleared · 2005-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k052381/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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