

K092711 GUARDIAN II HEMOSTASIS VALVEOct 1, 2009
28 days to decisionK092711 · Product code: **DTL** · Cardiovascular
Source: <https://www.510kdatabase.net/k092711/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Sep 3, 2009
Decision date	Oct 1, 2009
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zerusa Limited
Location	Galway, IE
Contact	LIAM MULLOY
510(k) history	4 submissions · 4 cleared · 2005-2010

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