

K101113 GUARDIAN II NC HEMOSTASIS VALVEMay 21, 2010
30 days to decisionK101113 · Product code: **DTL** · Cardiovascular
Source: <https://www.510kdatabase.net/k101113/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Apr 21, 2010
Decision date	May 21, 2010
Days to decision	30 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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