

**K122301 GUARDIAN II HEMOSTASIS VALVE GUARDIAN II NC
HEMOSTASIS VALVE**Sep 7, 2012
37 days to decisionK122301 · Product code: DTL · Cardiovascular
Source: <https://www.510kdatabase.net/k122301/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Aug 1, 2012
Decision date	Sep 7, 2012
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vascular Solutions Zerusa , Ltd.
Location	Minneapolis, MN, US
Contact	JENNIFER RUETHER
510(k) history	1 submissions · 1 cleared · 2012-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122301/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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