

K073620 GUARDIAN HEMOSTASIS VALVEFeb 27, 2008
63 days to decisionK073620 · Product code: **DTL** · Cardiovascular
Source: <https://www.510kdatabase.net/k073620/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Dec 26, 2007
Decision date	Feb 27, 2008
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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