

K092623 F.A.S.T. SYSTEM SED AND CXDOct 30, 2009
65 days to decisionK092623 · Product code: **QEW** · Cardiovascular
Source: <https://www.510kdatabase.net/k092623/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Aug 26, 2009
Decision date	Oct 30, 2009
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genesis Medical Interventional, Inc.
Location	Redwood City, CA, US
Contact	ANNE WORDEN
510(k) history	2 submissions · 2 cleared · 2004-2009

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