FDA 510(k) Premarket Notification

K091367 GDS-DCS

CLEARED

Nov 5, 2009
181 days to decision

K091367 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k091367/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	May 8, 2009
Decision date	Nov 5, 2009
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guided Delivery Systems**
Location	Santa Clara, CA, US
Contact	BONNIE MCINERNEY
510(k) history	2 submissions · 2 cleared · 2009-2010

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k091367/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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