

K111004 HANSEN MEDICAL VASCULAR CATHETER CONTROL SYSTEM AND CATHETER

May 29, 2012
414 days to decision

K111004 · Product code: **DXX** · Cardiovascular
Source: <https://www.510kdatabase.net/k111004/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Catheter Control, Steerable (DXX)
Date received	Apr 11, 2011
Decision date	May 29, 2012
Days to decision	414 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hansen Medical, Inc.
Location	Mountain View, CA, US
Contact	KATE WHITIN
510(k) history	14 submissions · 10 cleared · 2006-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k111004/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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