FDA 510(k) Premarket Notification

K042338 CORONARY PERIPHERAL AND RENAL STEERABLE GUIDEWIRE

CLEARED

Sep 16, 2004
17 days to decision

K042338 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k042338/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 30, 2004
Decision date	Sep 16, 2004
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lake Region Mfg., Inc.**
Location	Mchenry, IL, US
Contact	KAREN MORTENSEN
510(k) history	42 submissions · 42 cleared · 1977-2010

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k042338/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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