FDA 510(k) Premarket Notification

K094062 PERCU-PRO GUIDEWIRE

CLEARED

Sep 27, 2010
270 days to decision

K094062 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k094062/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 31, 2009
Decision date	Sep 27, 2010
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiosolutions, Inc.**
Location	Stoughton, MA, US
Contact	MICHELE LUCEY
510(k) history	4 submissions · 4 cleared · 2010-2014

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k094062/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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