FDA 510(k) Premarket Notification

K113454 14 WIRE STANDARD, 14 WIRE LS

CLEARED

Feb 24, 2012
95 days to decision

K113454 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k113454/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Nov 21, 2011
Decision date	Feb 24, 2012
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Micro Therapeutics, Inc.**
Location	Aliso Viejo, CA, US
Contact	GREGORY J GEISSINGER
510(k) history	51 submissions · 50 cleared · 1994-2012