FDA 510(k) Premarket Notification

K130104 GUIDEWIRE, PURSUER SERIES

CLEARED

Jun 13, 2013
149 days to decision

K130104 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k130104/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jan 15, 2013
Decision date	Jun 13, 2013
Days to decision	149 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Oscor, Inc.**
Location	Palm Harbor, FL, US
Contact	MILA DOSKOCIL
510(k) history	49 submissions · 46 cleared · 1979-2021