FDA 510(k) Premarket Notification

K153703 Guiding Catheter

CLEARED

May 12, 2016
141 days to decision

K153703 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k153703/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 23, 2015
Decision date	May 12, 2016
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Texasmedical Technologies, Inc.**
Location	El Paso, TX, US
Contact	Aaron Chiu
510(k) history	7 submissions · 7 cleared · 2015-2017