FDA 510(k) Premarket Notification

K171427 Heli-FX Applier, Heli-FX Guide, Ancillary EndoAnchor Cassette

CLEARED

Jun 13, 2017
29 days to decision

K171427 · Product code: **OTD** · Cardiovascular
Source: https://www.510kdatabase.net/k171427/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endovascular Suturing System (OTD)
Date received	May 15, 2017
Decision date	Jun 13, 2017
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Vascular, Inc.**
Location	Plymouth, MN, US
Contact	Burt Goodson
510(k) history	5 submissions · 5 cleared · 2016-2018