FDA 510(k) Premarket Notification

# K182957 Heli-FX EndoAnchor System

**CLEARED**

Nov 21, 2018
28 days to decision

K182957 · Product code: **OTD** · Cardiovascular
Source: https://www.510kdatabase.net/k182957/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Endovascular Suturing System (OTD) |
| Date received | Oct 24, 2018 |
| Decision date | Nov 21, 2018 |
| Days to decision | 28 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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