CLEARED

Jul 30, 2019
222 days to decision

K183547 Marinr Steerable Intracardiac Electrode Catheter, StableMapr Steerable Intracardiac Electrode Catheter, Torqr Intracardiac Electrode Catheter, Soloist Intracardiac Electrode Catheter

K183547 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k183547/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Dec 20, 2018
Decision date	Jul 30, 2019
Days to decision	222 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic**
Location	Minneapolis, MN, US
Contact	Matthew Lobeck
Website	http://www.medtronic.com/us-en/index.html
510(k) history	33 submissions · 33 cleared · 2007-2026

Medtronic is an American-Irish medical device company with operational headquarters in Minneapolis, Minnesota. The company operates globally across more than 150 countries and is the largest medical device company in the world by revenue. Medtronic has received FDA 510(k) clearances from total submissions since 2007. The company's regulatory portfolio is dominated by cardiovascular devices, including oxygenation systems, arterial filters, cardioplegia delivery systems, and catheter-based interventions. Medtronic also maintains a significant presence in orthopedic spinal s...