FDA 510(k) Premarket Notification

K981642 STABLEMAPR STEERABLE INTRACARDIAC CATHETERS

CLEARED

Aug 5, 1998
89 days to decision

K981642 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k981642/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	May 8, 1998
Decision date	Aug 5, 1998
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Cardiorhythm**
Location	San Jose, CA, US
Contact	KRISTEN HONL
510(k) history	5 submissions · 5 cleared · 1994-1998