FDA 510(k) Premarket Notification

K171277 Reprocessed Inquiry Steerable Diagnostic EP Catheter

CLEARED

Oct 23, 2017
175 days to decision

K171277 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k171277/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	May 1, 2017
Decision date	Oct 23, 2017
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Innovative Health, LLC**
Location	Scottsdale, AZ, US
Contact	Amy Stoklas-Oakes
510(k) history	48 submissions · 48 cleared · 2016-2024