FDA 510(k) Premarket Notification

CLEARED

K161769 Reprocessed Supreme Diagnostic Electrophysiology Catheters

Dec 6, 2016
161 days to decision

K161769 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k161769/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Jun 28, 2016
Decision date	Dec 6, 2016
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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