FDA 510(k) Premarket Notification

CLEARED

K181056 Reprocessed CS Diagnostic Electrophysiology Catheter

Jan 24, 2019
279 days to decision

K181056 · Product code: **NLH** · Cardiovascular
Source: https://www.510kdatabase.net/k181056/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Apr 20, 2018
Decision date	Jan 24, 2019
Days to decision	279 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Sustainability Solutions**
Location	Tempe, AZ, US
Contact	Mia McCorkel
510(k) history	31 submissions · 31 cleared · 2011-2025