K121913 REPROCESSED ULTRASOUND INTRACARDIAC ECHO CATHETER

CLEARED

Dec 20, 2012
171 days to decision

K121913 · Product code: **OWQ** · Cardiovascular
Source: https://www.510kdatabase.net/k121913/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Jul 2, 2012
Decision date	Dec 20, 2012
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Sustainability Solutions, Inc.**
Location	Phoenix, AZ, US
Contact	MOIRA BARTON-VARTY
510(k) history	2 submissions · 2 cleared · 2012-2013