

**K121913 REPROCESSED ULTRASOUND INTRACARDIAC ECHO
CATHETER**Dec 20, 2012
171 days to decisionK121913 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121913/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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