FDA 510(k) Premarket Notification

K063076 REPROCESSED DIAGNOSTIC ULTRASOUND CATHETER

CLEARED

Mar 29, 2007
174 days to decision

K063076 · Product code: **OWQ** · Cardiovascular
Source: https://www.510kdatabase.net/k063076/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Oct 6, 2006
Decision date	Mar 29, 2007
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ascent Healthcare Solutions**
Location	Phoenix, AZ, US
Contact	JENN SELVEY
510(k) history	21 submissions · 21 cleared · 2006-2011

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k063076/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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