

**K092425 REPROCESSED 3D DIAGNOSTIC ULTRASOUND
CATHETERS, MODEL SNDSTR10**Oct 21, 2009
75 days to decisionK092425 · Product code: **OWQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k092425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Aug 7, 2009
Decision date	Oct 21, 2009
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092425/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026