FDA 510(k) Premarket Notification

K092064 SOUNDSTAR 3D ULTRASOUND CATHETER, MODEL M-5723-12

CLEARED

Aug 7, 2009
30 days to decision

K092064 · Product code: **OBJ** · Cardiovascular
Source: https://www.510kdatabase.net/k092064/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Jul 8, 2009
Decision date	Aug 7, 2009
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biosense Webster, Inc.**
Location	Irvine, CA, US
Contact	MELISSA SCHULTZ
Website	https://www.jnjmedtech.com
510(k) history	73 submissions · 73 cleared · 1999-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k092064/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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