

K091352 SOUNDSTAR 3D DIAGNOSTIC CATHETER, MODEL M-5723-05Dec 4, 2009
211 days to decisionK091352 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k091352/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	May 7, 2009
Decision date	Dec 4, 2009
Days to decision	211 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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