

**K101138 SOUNDSTAR 3D ULTRASOUND CATHETER MODEL
M-5723-12**Jun 22, 2010
61 days to decisionK101138 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k101138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Apr 22, 2010
Decision date	Jun 22, 2010
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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