

K240050 SOUNDSTAR™ CRYSTAL Ultrasound CatheterJun 12, 2024
156 days to decisionK240050 · Product code: **OBJ** · CardiovascularSource: <https://www.510kdatabase.net/k240050/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Jan 8, 2024
Decision date	Jun 12, 2024
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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