

**K250545 Medline ReNewal Reprocessed Biosense Webster  
SOUNDSTAR eco Diagnostic Ultrasound Catheter (8F, 8FG,  
10F, 10FG)**Jun 5, 2025  
100 days to decisionK250545 · Product code: **OWQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k250545/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Feb 25, 2025
Decision date	Jun 5, 2025
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Surgical Instrument Service and Savings, Inc.</b>
Location	Redmond, OR, US
Contact	Stephanie Boyle Mays
510(k) history	23 submissions · 23 cleared · 2016-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250545/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026