

**K101991 WEBSTER DUO-DECAPOLAR CATHETER**May 2, 2011  
292 days to decisionK101991 · Product code: **DRF** · CardiovascularSource: <https://www.510kdatabase.net/k101991/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Jul 14, 2010
Decision date	May 2, 2011
Days to decision	292 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101991/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 19, 2026