

**K170997 CARTO VIZIGO 8.5F Bi-Directional Guiding Sheath**Jul 25, 2017  
113 days to decisionK170997 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k170997/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 3, 2017
Decision date	Jul 25, 2017
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biosense Webster, Inc.</b>
Location	Irvine, CA, US
Contact	John Jimenez
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/k170997/> 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 1, 2026