

**K231412 CARTO VIZIGO® 8.5F Bi-Directional Guiding Sheath
(D-1385-01-S, D-1385-02-S, D-1385-03-S)**Jul 10, 2023
55 days to decisionK231412 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k231412/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	May 16, 2023
Decision date	Jul 10, 2023
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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