

K120425 PENTARAY NAV HIGH-DENSITY MAPPING CATHETERMay 24, 2012
101 days to decisionK120425 · Product code: **MTD** · CardiovascularSource: <https://www.510kdatabase.net/k120425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intracardiac Mapping, High-density Array (MTD)
Date received	Feb 13, 2012
Decision date	May 24, 2012
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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