

**K211438 OPTRELL Mapping Catheter with TRUEref Technology**Mar 18, 2022  
312 days to decisionK211438 · Product code: **MTD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k211438/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intracardiac Mapping, High-density Array (MTD)
Date received	May 10, 2021
Decision date	Mar 18, 2022
Days to decision	312 days
Third-party review	No
Combination product	No
PCCP authorized	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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