

K193237 Carto Octaray Mapping Catheter with Trueref TechnologyJul 31, 2020
249 days to decisionK193237 · Product code: **MTD** · Cardiovascular
Source: <https://www.510kdatabase.net/k193237/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intracardiac Mapping, High-density Array (MTD)
Date received	Nov 25, 2019
Decision date	Jul 31, 2020
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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