FDA 510(k) Premarket Notification

CLEARED

K230253 OPTRELL™ Mapping Catheter with TRUEref™ Technology

Mar 2, 2023
30 days to decision

K230253 · Product code: **MTD** · Cardiovascular
Source: https://www.510kdatabase.net/k230253/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intracardiac Mapping, High-density Array (MTD)
Date received	Jan 31, 2023
Decision date	Mar 2, 2023
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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