FDA 510(k) Premarket Notification

K061468 REFSTAR EXTERNAL REFERENCE PATCH

CLEARED

Aug 14, 2006
80 days to decision

K061468 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k061468/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	May 26, 2006
Decision date	Aug 14, 2006
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k061468/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026