FDA 510(k) Premarket Notification

K042998 REFSTAR RMT EXTERNAL REFERENCE PATCH

CLEARED

Sep 29, 2005
332 days to decision

K042998 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k042998/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Nov 1, 2004
Decision date	Sep 29, 2005
Days to decision	332 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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