FDA 510(k) Premarket Notification

K081258 VARIABLE LASSO NAV CATHETER, MODELS: D-1290-01, D-1290-02

CLEARED

Jan 6, 2009
249 days to decision

K081258 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k081258/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	May 2, 2008
Decision date	Jan 6, 2009
Days to decision	249 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