FDA 510(k) Premarket Notification

K052083 NAVISTAR RMT STEERABLE TIP DIAGNOSTIC CATHETER

CLEARED

Sep 29, 2005
58 days to decision

K052083 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k052083/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Aug 2, 2005
Decision date	Sep 29, 2005
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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