FDA 510(k) Premarket Notification

K080425 CS REFSTAR CATHETER (D- AND F-CURVES), MODELS D-1285-01 AND D-1285-02

CLEARED

Apr 23, 2008
68 days to decision

K080425 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k080425/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Feb 15, 2008
Decision date	Apr 23, 2008
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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