FDA 510(k) Premarket Notification

K913375 TORQUE TUBE STEEROCATH(TM)

CLEARED

Oct 25, 1991
88 days to decision

K913375 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k913375/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Jul 29, 1991
Decision date	Oct 25, 1991
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ep Technologies, Inc.**
Location	Mountain View, CA, US
Contact	LINDA COOPERMAN
510(k) history	15 submissions · 15 cleared · 1988-2005

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k913375/ 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 July 3, 2026