FDA 510(k) Premarket Notification

K932388 HRT SERIES 100 ELECTROPHYSIOLOGY CATHETER

CLEARED

May 31, 1995
744 days to decision

K932388 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k932388/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	May 17, 1993
Decision date	May 31, 1995
Days to decision	744 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Heart Rhythm Technologies, Inc.**
Location	Temecula, CA, US
Contact	MIRAIM TAIMISTO
510(k) history	1 submissions · 1 cleared · 1995-1995

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k932388/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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