FDA 510(k) Premarket Notification

K092744 NEONATAL ECG ELECTRODE, M203KEN

CLEARED

Dec 10, 2009
93 days to decision

K092744 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k092744/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Sep 8, 2009
Decision date	Dec 10, 2009
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**R & D Medical Products, Inc.**
Location	Lake Forest, CA, US
Contact	JAMES PERRAULT
510(k) history	4 submissions · 4 cleared · 1998-2011

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k092744/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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