FDA 510(k) Premarket Notification

K940802 ZIPPREP ELECTRODE

CLEARED

Jun 22, 1994
120 days to decision

K940802 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k940802/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Feb 22, 1994
Decision date	Jun 22, 1994
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aspect Medical Systems, Inc.**
Location	Framingham, MA, US
Contact	CHRISTINE MORGIDA
510(k) history	25 submissions · 25 cleared · 1992-2009

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k940802/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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