FDA 510(k) Premarket Notification

K040183 BISX

CLEARED

Feb 25, 2004
29 days to decision

K040183 · Product code: **OLW** · Neurology
Source: https://www.510kdatabase.net/k040183/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Jan 27, 2004
Decision date	Feb 25, 2004
Days to decision	29 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k040183/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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