

K031694 MODIFICATION TO EEG MONITOR WITH BIS, MODEL A-2000Aug 29, 2003
88 days to decisionK031694 · Product code: **OLW** · Neurology
Source: <https://www.510kdatabase.net/k031694/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Jun 2, 2003
Decision date	Aug 29, 2003
Days to decision	88 days
Third-party review	No
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.netDevice record: <https://www.510kdatabase.net/k031694/> 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 June 22, 2026