

K011534 EEG MIS MONITOR MODEL # A-2000

Jun 15, 2001
28 days to decision

K011534 · Product code: **OLW** · Neurology
Source: <https://www.510kdatabase.net/k011534/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	May 18, 2001
Decision date	Jun 15, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary
Other names	BIS ENGINE

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k011534/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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