FDA 510(k) Premarket Notification

K011834 BIS ENGINE

CLEARED

Jul 10, 2001
28 days to decision

K011834 · Product code: **OLW** · Neurology
Source: https://www.510kdatabase.net/k011834/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Jun 12, 2001
Decision date	Jul 10, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

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/k011834/ 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