

K023209 INSIGHT MILLENNIUM IIIOct 10, 2003
379 days to decisionK023209 · Product code: **IKN** · Neurology
Source: <https://www.510kdatabase.net/k023209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electromyograph, Diagnostic (IKN)
Date received	Sep 26, 2002
Decision date	Oct 10, 2003
Days to decision	379 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fasstech
Location	Burlington, MA, US
Contact	LEE BRODY
510(k) history	9 submissions · 9 cleared · 1993-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k023209/> 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 27, 2026