

K011964 INSIGHT MILLENNIUM PLUSSep 20, 2001
87 days to decisionK011964 · Product code: **HCC** · Neurology
Source: <https://www.510kdatabase.net/k011964/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Biofeedback (HCC)
Date received	Jun 25, 2001
Decision date	Sep 20, 2001
Days to decision	87 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/k011964/> 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