

K063447 INSIGHT DISCOVERYAug 16, 2007
274 days to decisionK063447 · Product code: **IKN** · Neurology
Source: <https://www.510kdatabase.net/k063447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electromyograph, Diagnostic (IKN)
Date received	Nov 15, 2006
Decision date	Aug 16, 2007
Days to decision	274 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

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