FDA 510(k) Premarket Notification

K011964 INSIGHT MILLENNIUM PLUS

CLEARED

Sep 20, 2001
87 days to decision

K011964 · 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