FDA 510(k) Premarket Notification

K011983 INSIGHT GENESIS

CLEARED

Aug 30, 2001
65 days to decision

K011983 · Product code: **HCC** · Neurology
Source: https://www.510kdatabase.net/k011983/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Biofeedback (HCC)
Date received	Jun 26, 2001
Decision date	Aug 30, 2001
Days to decision	65 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