FDA 510(k) Premarket Notification

K183123 microTargeting Guideline 4000 5.0 System

CLEARED

Dec 20, 2018
37 days to decision

K183123 · Product code: **GZL** · Neurology
Source: https://www.510kdatabase.net/k183123/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Depth (GZL)
Date received	Nov 13, 2018
Decision date	Dec 20, 2018
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**FHC, Inc.**
Location	Bowdoinham, ME, US
Contact	Kelly Moeykens
510(k) history	12 submissions · 12 cleared · 2000-2023