

K183123 microTargeting Guideline 4000 5.0 SystemDec 20, 2018
37 days to decisionK183123 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183123/> 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 May 26, 2026