

K222706 iCE-SG2 Subcutaneous Electrode KitDec 6, 2022
90 days to decisionK222706 · Product code: **GZL** · Neurology
Source: <https://www.510kdatabase.net/k222706/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Depth (GZL)
Date received	Sep 7, 2022
Decision date	Dec 6, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ice Neurosystems, Inc.
Location	Washington, DC, US
Contact	Emir Kapetanovic
510(k) history	3 submissions · 3 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Allison Komiyama

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222706/> 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 24, 2026