

**K201678 iCE-SG Subcutaneous Electrode Arrays**Mar 8, 2021  
262 days to decisionK201678 · Product code: **GZL** · Neurology  
Source: <https://www.510kdatabase.net/k201678/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Depth (GZL)
Date received	Jun 19, 2020
Decision date	Mar 8, 2021
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ice Neurosystems, Inc.</b>
Location	Washington, DC, US
Contact	Allen Waziri
510(k) history	3 submissions · 3 cleared · 2020-2022

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Acknowledge Regulatory Strategies, LLC</b>
Contact	Allison C Komiyama

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201678/> 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