

**K250363 Depth Electrode (RSDE-08)**

Nov 5, 2025  
268 days to decision

K250363 · Product code: **GZL** · Neurology  
Source: <https://www.510kdatabase.net/k250363/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Depth (GZL)
Date received	Feb 10, 2025
Decision date	Nov 5, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Depth Electrode (RSDE-10); Depth Electrode (RSDE-12); Depth Electrode (RSDE-14); Depth Electrode (RSDE-16); Depth Electrode (RSDE-16F); Depth Electrode (RSDE-08S); Depth Electrode (RSDE-10S); Depth Electrode (RSDE-12S); Depth Electrode (RSDE-14S); Depth Electrode (RSDE-16S); Depth Electrode (RSDE-16G); Depth Electrode (RSDE-18); Depth Electrode (RSDE-18F); Depth Electrode (RSDE-18T); Depth Electrode (RSDE-20); Depth Electrode (RSDE-20F); Dept

**APPLICANT**

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Company	<b>Beijing Sinovation Medical Technology Co., Ltd.</b>
Location	Beijing, CN
Contact	Lina Wang
510(k) history	1 submissions · 1 cleared · 2025-2025

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