

K232581 Medical Disposable Sterile Needle ElectrodeDec 4, 2023
101 days to decisionK232581 · Product code: **GXZ** · Neurology
Source: <https://www.510kdatabase.net/k232581/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Needle (GXZ)
Date received	Aug 25, 2023
Decision date	Dec 4, 2023
Days to decision	101 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Haishen Medical Device Associates Co., Ltd.
Location	Suzhou, CN
Contact	Leyi Dai
510(k) history	2 submissions · 2 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Sinow Medical AS
Contact	Jie Gao

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232581/> 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