FDA 510(k) Premarket Notification

K232581 Medical Disposable Sterile Needle Electrode

CLEARED

Dec 4, 2023
101 days to decision

K232581 · 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