

K232888 Disposable Laryngeal ElectrodesDec 21, 2023
94 days to decisionK232888 · Product code: **ETN** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k232888/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve (ETN)
Date received	Sep 18, 2023
Decision date	Dec 21, 2023
Days to decision	94 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	Xiaoqing Xue

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/k232888/> 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