

K230853 EARP Nerve Cuff ElectrodeOct 6, 2023
192 days to decisionK230853 · Product code: **ETN** · Neurology
Source: <https://www.510kdatabase.net/k230853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve (ETN)
Date received	Mar 28, 2023
Decision date	Oct 6, 2023
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nvision Biomedical Technologies, Inc.
Location	San Antonio, TX, US
Contact	Diana Langham
510(k) history	24 submissions · 24 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	Watershed Idea Foundry
Contact	Jeffrey Brittan

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

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