

K232242 BEAR 2 BodyMay 13, 2024
290 days to decisionK232242 · Product code: **NFO** · Neurology
Source: <https://www.510kdatabase.net/k232242/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	Jul 28, 2023
Decision date	May 13, 2024
Days to decision	290 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Foreo, Inc.
Location	Las Vegas, NV, US
Contact	Evan Feldstein
510(k) history	10 submissions · 10 cleared · 2016-2026

REGULATORY CONSULTANT

Consulting firm	DD Consulting
Contact	Danijela Domljanovic

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/k232242/> 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 14, 2026