

K201906 Trinity ELE Plus and Trinity ELE Plus ProFeb 24, 2021
230 days to decisionK201906 · Product code: **NFO** · Neurology
Source: <https://www.510kdatabase.net/k201906/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	Jul 9, 2020
Decision date	Feb 24, 2021
Days to decision	230 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Carol Cole Company Db a Nuface
Location	Vista, CA, US
Contact	Danielle Barker Fernandes
510(k) history	8 submissions · 8 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	Bob Duffy Associates, Inc.
Contact	Bob Duffy

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201906/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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