

K201782 NuFace Trinity Plus DeviceJan 22, 2021
206 days to decisionK201782 · Product code: **NFO** · Neurology
Source: <https://www.510kdatabase.net/k201782/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	Jun 30, 2020
Decision date	Jan 22, 2021
Days to decision	206 days
Third-party review	No
Combination product	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/k201782/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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