FDA 510(k) Premarket Notification

K181008 NuFACE Trinity

CLEARED

Oct 11, 2018
177 days to decision

K181008 · Product code: **NFO** · Neurology
Source: https://www.510kdatabase.net/k181008/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	Apr 17, 2018
Decision date	Oct 11, 2018
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Carol Cole Company Dba Nuface**
Location	Vista, CA, US
Contact	Donald Ellis
510(k) history	8 submissions · 8 cleared · 2017-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k181008/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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