

K212947 Trinity Plus Wrinkle ReducerApr 2, 2022
199 days to decisionK212947 · Product code: **OHS** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k212947/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Sep 15, 2021
Decision date	Apr 2, 2022
Days to decision	199 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	David Reece
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/k212947/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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