

K213841 ENEO TOTALE (Model: ENEOT947)Jan 6, 2022
28 days to decisionK213841 · Product code: **OHS** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k213841/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Dec 9, 2021
Decision date	Jan 6, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Premier North America, Inc.
Location	Fort Lauderdale, FL, US
Contact	Ellis Tamari
510(k) history	6 submissions · 6 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	Shanghai CV Technology Co., Ltd.
Contact	Doris Dong

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

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