

K232656 BLU TOTALE (Model: ENEOB852)Nov 14, 2023
75 days to decisionK232656 · Product code: **OLP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k232656/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Powered Light Based Laser For Acne (OLP)
Date received	Aug 31, 2023
Decision date	Nov 14, 2023
Days to decision	75 days
Third-party review	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

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