

K162450 ESPADA Acne-Clearing Blue Light PenNov 30, 2016
90 days to decisionK162450 · Product code: **OLP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162450/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Powered Light Based Laser For Acne (OLP)
Date received	Sep 1, 2016
Decision date	Nov 30, 2016
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Foreo, Inc.
Location	Las Vegas, NV, US
Contact	Davor Soldo
510(k) history	10 submissions · 10 cleared · 2016-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162450/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026