

**K172555 SAPPHIRE, ELEVARE SAPPHIRE**May 1, 2018  
250 days to decisionK172555 · Product code: **OLP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k172555/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Powered Light Based Laser For Acne (OLP)
Date received	Aug 24, 2017
Decision date	May 1, 2018
Days to decision	250 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omm Imports, Inc. D/B/A Zero Gravity</b>
Location	Doral, FL, US
Contact	Zivan Habibi
510(k) history	2 submissions · 2 cleared · 2018-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Aegis, Inc.</b>
Contact	Susan Anthony-DeWet

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172555/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026