

**K250384 IPL400**May 23, 2025  
101 days to decisionK250384 · Product code: **OHT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250384/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Feb 11, 2025
Decision date	May 23, 2025
Days to decision	101 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>EI Global Trade, Ltd.</b>
Location	Netanya, IL
Contact	Stephanie Khoury
510(k) history	11 submissions · 11 cleared · 2014-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250384/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026