

**K183329 Laser Hair Therapy**Jan 16, 2019  
47 days to decisionK183329 · Product code: **OAP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k183329/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Comb, Hair (OAP)
Date received	Nov 30, 2018
Decision date	Jan 16, 2019
Days to decision	47 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	Moti Shenfarber
510(k) history	2 submissions · 2 cleared · 2018-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Feiyang Drug &amp; Medical Consulting Technical Service Group</b>
Contact	Rain Yip

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/k183329/> 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