

**K161046 Laser Helmet LH40-EVO**May 12, 2016  
29 days to decisionK161046 · Product code: **OAP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161046/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laser, Comb, Hair (OAP)
Date received	Apr 13, 2016
Decision date	May 12, 2016
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Theradome, Inc.</b>
Location	Summerville, SC, US
Contact	Tamim Hamid
510(k) history	5 submissions · 5 cleared · 2012-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161046/> 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 30, 2026