

**K091446 MODIFICATION TO LUX1540 HANDPIECE AND LUX
1440 HANDPIECE**Oct 27, 2009
165 days to decisionK091446 · Product code: **ONG** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k091446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument With Microbeamfractional Output (ONG)
Date received	May 15, 2009
Decision date	Oct 27, 2009
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Palomar Medical Products, Inc.
Location	Cary, NC, US
Contact	SHARON TIMBERLAKE, RAC, CCRA
510(k) history	21 submissions · 21 cleared · 1998-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091446/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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