

K162371 Pulsaderm ACE-All BlueDec 15, 2016
113 days to decisionK162371 · Product code: **OLP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162371/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Powered Light Based Laser For Acne (OLP)
Date received	Aug 24, 2016
Decision date	Dec 15, 2016
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nutra Luxe MD, LLC
Location	Sparks, NV, US
Contact	Gloria Avendano
510(k) history	9 submissions · 9 cleared · 2014-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162371/> Data sourced from FDA 510(k) public records (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. - Generated June 2, 2026