

K160012 O-pel Laser and families of probe delivery devicesJun 2, 2016
150 days to decisionK160012 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k160012/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 4, 2016
Decision date	Jun 2, 2016
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Precise Light Surgical
Location	Campbell, CA, US
Contact	KEN ARNOLD
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160012/> 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