

K202175 OxyLight 2.0Dec 2, 2021
485 days to decisionK202175 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k202175/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 4, 2020
Decision date	Dec 2, 2021
Days to decision	485 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Raja Trading Company, Inc.
Location	West Palm Beach, FL, US
Contact	Christine K. Powers
510(k) history	3 submissions · 3 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	Smith Associates
Contact	Yolanda R. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202175/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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