

K203491 PicoLO Nd: YAG Picosecond Laser SystemApr 7, 2021
131 days to decisionK203491 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k203491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 27, 2020
Decision date	Apr 7, 2021
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Laseroptek Co., Ltd.
Location	Torrance, CA, US
Contact	Hong Chu
510(k) history	13 submissions · 13 cleared · 2009-2025

REGULATORY CONSULTANT

Consulting firm	Bt Solutions, Inc.
Contact	Do Hyun Kim

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

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