FDA 510(k) Premarket Notification

K212573 PicoLO Premium

CLEARED

Dec 8, 2021
114 days to decision

K212573 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212573/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 16, 2021
Decision date	Dec 8, 2021
Days to decision	114 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