FDA 510(k) Premarket Notification

K230373 HELIOS 785 Pico

CLEARED

May 22, 2023
98 days to decision

K230373 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k230373/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 13, 2023
Decision date	May 22, 2023
Days to decision	98 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	Wonmi Lee

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