

**K212663 HELIOS IV 785**Jun 9, 2022  
290 days to decisionK212663 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212663/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 23, 2021
Decision date	Jun 9, 2022
Days to decision	290 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Bt Solutions, Inc.</b>
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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