

**K243780 HELIOS 785 Pico (1754V2)**Feb 7, 2025  
60 days to decisionK243780 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k243780/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 9, 2024
Decision date	Feb 7, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Bt Solutions, Inc.</b>
Contact	Kim Do Hyun

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243780/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026