

K252319 Q-Switched Nd: YAG Laser machine (LFS-C13U)Oct 20, 2025
87 days to decisionK252319 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 25, 2025
Decision date	Oct 20, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sanhe Lefis Electronics Co., Ltd.
Location	Langfang, CN
Contact	Dandan Wang
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Sanhe Lefis Electronics Co., Ltd.
Contact	Dandan Wang

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.netDevice record: <https://www.510kdatabase.net/k252319/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026