

K250998 CO2 Laser Therapy System (Model: LFS-D9U)Dec 19, 2025
262 days to decisionK250998 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k250998/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 1, 2025
Decision date	Dec 19, 2025
Days to decision	262 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/k250998/> 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