

K252427 Diode Laser Hair Removal Machine (GLD01)Oct 31, 2025
91 days to decisionK252427 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 1, 2025
Decision date	Oct 31, 2025
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sanhe Meditech Co., Ltd.
Location	Sanhe, CN
Contact	Xiaoxia Song
510(k) history	2 submissions · 2 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252427/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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