

K252063 Medical Diode Laser Systems (BERYLAS-12N)Sep 25, 2025
86 days to decisionK252063 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 1, 2025
Decision date	Sep 25, 2025
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Medical Diode Laser Systems (BERYLAS-15N); Medical Diode Laser Systems (HARLAS-45JN); Medical Diode Laser Systems (HARLAS-46JN)

APPLICANT

Company	Wuhan Dimed Laser Technology Co., Ltd.
Location	Wuhan, CN
Contact	Qiao Cheng
510(k) history	2 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Linnwell International Certification Consulting Co., Ltd.
Contact	Yuling Chen

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/k252063/> 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 13, 2026