

K220381 Diode Laser Therapy SystemsMay 20, 2022
99 days to decisionK220381 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220381/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 10, 2022
Decision date	May 20, 2022
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beijing Lasertell Medical Co., Ltd.
Location	Beijing, CN
Contact	Zeng Xun
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

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

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