

**K212733 Diode laser therapy device**Jun 6, 2023  
645 days to decisionK212733 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k212733/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 30, 2021
Decision date	Jun 6, 2023
Days to decision	645 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beijing Star New Tech Co., Ltd.</b>
Location	Beijing, CN
Contact	Liang ZhongDong
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Truthful Information Technology Co., Ltd.</b>
Contact	Boyle 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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