

**K212478 Dermatological diode laser system**Jan 14, 2022  
158 days to decisionK212478 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k212478/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 9, 2021
Decision date	Jan 14, 2022
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beijing Stelle Laser Technology Co., Ltd.</b>
Location	Beijing, CN
Contact	Zhao Changcheng
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Beijing Believe-Med Technology Service Co., Ltd.</b>
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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