

**K210168 Diode Laser Therapy Systems**May 10, 2021  
108 days to decisionK210168 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k210168/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 22, 2021
Decision date	May 10, 2021
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beijing Kes Biology Technology Co., Ltd.</b>
Location	Shanghai, CN
Contact	Wei Meng Meng
510(k) history	3 submissions · 3 cleared · 2013-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
Contact	Diana Hong

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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