

**K211977 Medical Diode Laser Systems**Oct 26, 2021  
123 days to decisionK211977 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211977/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 25, 2021
Decision date	Oct 26, 2021
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Hlongmed Biotech Co., Ltd.</b>
Contact	Long Yang

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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