

**K211335 Diode Laser Machine, Model Number: BM-100**Jul 28, 2021  
86 days to decisionK211335 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211335/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 3, 2021
Decision date	Jul 28, 2021
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhengzhou Bestview ST Co., Ltd.</b>
Location	Zhengzhou, CN
Contact	Yangchun Jia
510(k) history	2 submissions · 2 cleared · 2021-2021

**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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