

K211735 CO2 Laser Machine, Model: BW-203BOct 22, 2021
137 days to decisionK211735 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k211735/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 7, 2021
Decision date	Oct 22, 2021
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211735/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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