

K240386 Picosecond Nd:YAG Laser Systems (BL-C10)May 16, 2024
98 days to decisionK240386 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k240386/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 8, 2024
Decision date	May 16, 2024
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Bele Medical Technology Co.,Ltd
Location	Shanghai, CN
Contact	Jeremy Li
510(k) history	3 submissions · 3 cleared · 2023-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240386/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026