

K243993 Photon Therapy Apparatus (BL-10)Mar 13, 2025
77 days to decisionK243993 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243993/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 26, 2024
Decision date	Mar 13, 2025
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xemis Medical Technology (Shenzhen) Co., Ltd.
Location	Shenzhen, CN
Contact	Yongfen Yang
510(k) history	2 submissions · 2 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243993/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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