

K243957 PICOALEXMar 12, 2025
79 days to decisionK243957 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243957/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 23, 2024
Decision date	Mar 12, 2025
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wontech Co., Ltd.
Location	Daejeon, KR
Contact	Hyunsik Yoon
510(k) history	28 submissions · 28 cleared · 2017-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243957/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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