

K223727 LavieenAug 25, 2023
255 days to decisionK223727 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223727/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 13, 2022
Decision date	Aug 25, 2023
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223727/> 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 14, 2026