

K242206 ACTIVOSep 27, 2024
60 days to decisionK242206 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 29, 2024
Decision date	Sep 27, 2024
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Daeju Meditech Engineering Co., Ltd.
Location	Seoul, KR
Contact	Kim Seongun
510(k) history	3 submissions · 3 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Withus Group, Inc.
Contact	Lee April

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242206/> 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