FDA 510(k) Premarket Notification

K242206 ACTIVO

CLEARED

Sep 27, 2024
60 days to decision

K242206 · Product code: **GEX** · General & Plastic Surgery
Source: 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