

K251464 TRI-BEAM PRO, TRI-BEAM (Nd:YAG Laser unit)

Oct 3, 2025
143 days to decision

K251464 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k251464/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 13, 2025
Decision date	Oct 3, 2025
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jeisys Medical Incorporated
Location	Seoul, KR
Contact	Jeongwook Lee
510(k) history	3 submissions · 3 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	E & M
Contact	Sanghwa Myung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)
