FDA 510(k) Premarket Notification

K260489 LASEmaR 1500

CLEARED

May 29, 2026
105 days to decision

K260489 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k260489/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 13, 2026
Decision date	May 29, 2026
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Eufoton S.R.L.**
Location	Trieste, IT
Contact	Andrea Buoso
510(k) history	2 submissions · 2 cleared · 2010-2026