

K241656 Eneka SelectifAug 12, 2024
63 days to decisionK241656 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241656/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 10, 2024
Decision date	Aug 12, 2024
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Termosalud
Location	Gijon, ES
Contact	Cristina Cifuentes
510(k) history	5 submissions · 5 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Hoy & Associates Regulatory Consulting
Contact	Aubrey Thompson

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/k241656/> 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 13, 2026