

**K223680 Eneka Pro**Feb 10, 2023  
64 days to decisionK223680 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223680/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 8, 2022
Decision date	Feb 10, 2023
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hoy and Associates Regulatory Consulting</b>
Contact	Connie Hoy

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223680/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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