FDA 510(k) Premarket Notification

K223680 Eneka Pro

CLEARED

Feb 10, 2023
64 days to decision

K223680 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k223680/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Hoy and Associates Regulatory Consulting**
Contact	Connie Hoy

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