

K222221 DEKA HELIXJan 4, 2023
163 days to decisionK222221 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k222221/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 25, 2022
Decision date	Jan 4, 2023
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	EI.En Electronic Engineering Spa
Location	Calenzano, IT
Contact	Paolo Peruzzi
510(k) history	27 submissions · 27 cleared · 2007-2023

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