

K202258 ERISE Laser handpieceApr 26, 2021
259 days to decisionK202258 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k202258/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 10, 2020
Decision date	Apr 26, 2021
Days to decision	259 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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