

K213889 PicoStarApr 22, 2022
130 days to decisionK213889 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213889/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 13, 2021
Decision date	Apr 22, 2022
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Asclepion Laser Technologies GmbH
Location	Chelmsford, MA, US
Contact	Carolin Kuehling
510(k) history	29 submissions · 29 cleared · 2004-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213889/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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