

K230077 LaserMEJul 17, 2023
188 days to decisionK230077 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 10, 2023
Decision date	Jul 17, 2023
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neauvia North America
Location	Raleigh, NC, US
Contact	Joy Willard
510(k) history	3 submissions · 3 cleared · 2021-2023

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