

K213261 EpilMEJun 2, 2022
245 days to decisionK213261 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 30, 2021
Decision date	Jun 2, 2022
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213261/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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