

K233143 PiXeI8-RevealFeb 2, 2024
128 days to decisionK233143 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233143/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 27, 2023
Decision date	Feb 2, 2024
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rohrer Aesthetics
Location	Birmingham, AL, US
Contact	Mark Rohrer
510(k) history	2 submissions · 2 cleared · 2023-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233143/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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