

K232858 ORskin BlueMay 1, 2024
229 days to decisionK232858 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k232858/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 15, 2023
Decision date	May 1, 2024
Days to decision	229 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Megabay S.A.
Location	Ciudad Aut?noma De Buenos Aires, AR
Contact	Oren Gabay
510(k) history	1 submissions · 1 cleared · 2024-2024

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