

K233304 Omnimax S3, Omnimax S4Dec 22, 2023
84 days to decisionK233304 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233304/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 29, 2023
Decision date	Dec 22, 2023
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sharplight Technologies, Ltd.
Location	Zichron Yaacov, IL
Contact	Rada Trifonov
510(k) history	4 submissions · 4 cleared · 2008-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233304/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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