

**K234004 Medical diode laser systems (CHARISMA, REGAL)**Feb 20, 2025  
429 days to decisionK234004 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k234004/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 19, 2023
Decision date	Feb 20, 2025
Days to decision	429 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Reveal Lasers , Ltd.</b>
Location	Aviv, IL
Contact	Mike Collette
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k234004/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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