

**K252753 Vydenze Family of Lasers**Jan 24, 2026  
148 days to decisionK252753 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252753/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 29, 2025
Decision date	Jan 24, 2026
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vydenze Medical Industria E Comercio Ltda</b>
Location	Sal Carlos, BR
Contact	Eduardo Gabriel
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hoy &amp; Associates Regulatory Consulting, LLC</b>
Contact	Connie Hoy

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252753/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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