

**K240159 InnoVoyce VYLO**May 29, 2024  
131 days to decisionK240159 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k240159/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 19, 2024
Decision date	May 29, 2024
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Innovoyce</b>
Location	Boston, MA, US
Contact	Stephen Mais
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Hoy and Associates Regulatory Consulting</b>
Contact	Thompson Aubrey

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240159/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026