

K251100 IPGTFL-02Sep 19, 2025
162 days to decisionK251100 · Product code: **GEX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k251100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 10, 2025
Decision date	Sep 19, 2025
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ipg Medical Corporation
Location	Marlborough, MA, US
Contact	Kevin O'Connell
510(k) history	2 submissions · 2 cleared · 2024-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251100/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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