

K955758 INDIGO MEDICAL MODEL IDL 830EFeb 16, 1996
59 days to decisionK955758 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k955758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 19, 1995
Decision date	Feb 16, 1996
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Indigo Medical, Inc.
Location	Palo Alto, CA, US
Contact	ALEX AXELROD
510(k) history	6 submissions · 6 cleared · 1996-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k955758/> 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 19, 2026