

**K963081 INDIGO MEDICAL MODEL IDL 830 & MODEL IDL 830E
LASER SYSTEMS FOR GENERAL GYNECOLOGICAL
APPLICATIONS**Feb 21, 1997
197 days to decisionK963081 · Product code: **GEX** · General & Plastic Surgery
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 8, 1996
Decision date	Feb 21, 1997
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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