

K971193 LASEAWAY LONG PULSE AND Q-SWITCHED RUBY LASER SYSTEMJun 24, 1997
84 days to decisionK971193 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k971193/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 1, 1997
Decision date	Jun 24, 1997
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Polytec Pi, Inc.
Location	Auburn, MA, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	2 submissions · 2 cleared · 1994-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971193/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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