

K950351 CL-5500 (UNMODIFIED DEVICE) PRECISION CURING UNIT (PCU) (MODIFIED OPTION)Mar 24, 1995
53 days to decisionK950351 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k950351/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 30, 1995
Decision date	Mar 24, 1995
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ion Laser Technology
Location	Salt Lake City, UT, US
Contact	J. R KEMPLE
510(k) history	9 submissions · 9 cleared · 1991-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950351/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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