

K882952 CO2 SURGICAL LASER SYSTEM MODEL #IR106Nov 2, 1988
111 days to decisionK882952 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k882952/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Jul 14, 1988 |
| Decision date | Nov 2, 1988 |
| Days to decision | 111 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Niic U.S.A., Inc. |
| Location | Redwood City, CA, US |
| Contact | JUN NISHIMURA |
| 510(k) history | 16 submissions · 16 cleared · 1988-1990 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k882952/>; 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 July 2, 2026