

K950831 ALEXLAZRMay 26, 1995
91 days to decisionK950831 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k950831/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Feb 24, 1995 |
| Decision date | May 26, 1995 |
| Days to decision | 91 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Candela Laser Corp. |
| Location | Wayland, MA, US |
| Contact | LISA M PARTHREE |
| 510(k) history | 43 submissions · 43 cleared · 1988-1996 |

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