

K964074 DIOLITE 532Apr 1, 1997
172 days to decisionK964074 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k964074/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Oct 11, 1996 |
| Decision date | Apr 1, 1997 |
| Days to decision | 172 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Iriderm Div. |
| Location | Mountain View, CA, US |
| Contact | THEODORE A BOUTACOFF |
| 510(k) history | 10 submissions · 10 cleared · 1989-1997 |

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