

K983058 CERALAS D LASER SYSTEM, MODEL # CERALAS D15Oct 21, 1998
50 days to decisionK983058 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k983058/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Sep 1, 1998 |
| Decision date | Oct 21, 1998 |
| Days to decision | 50 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ceram Optec, Inc. |
| Location | Washington, DC, US |
| Contact | JONATHAN S KAHAN |
| 510(k) history | 30 submissions · 30 cleared · 1992-2000 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983058/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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