

**K962948 CERALAS G ND**Oct 25, 1996  
88 days to decisionK962948 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k962948/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Jul 29, 1996                            |
| Decision date         | Oct 25, 1996                            |
| Days to decision      | 88 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |
| Other names           | YAG LASER SYSTEM (CERALAS G)            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ceram Optec, Inc.</b>                |
| Location       | Washington, DC, US                      |
| Contact        | CAROL J MORELLO, VMD                    |
| 510(k) history | 30 submissions · 30 cleared · 1992-2000 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k962948/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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