

**K052777 LASEREX DUO FAMILY OF DUAL WAVELENGTH
OPHTHALMIC LASERS INCLUDING MODELS INTEGRE DUO
LP1RG-S, LP1RG-D**Mar 16, 2006
164 days to decisionK052777 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k052777/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Oct 3, 2005 |
| Decision date | Mar 16, 2006 |
| Days to decision | 164 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Ellex Medical Pty, Ltd. |
| Location | Adelaide, South Australia, AU |
| Contact | KEVIN HOWARD |
| 510(k) history | 13 submissions · 13 cleared · 1997-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052777/> 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 May 26, 2026