

**K014100 OPUS SPECTRUM (A MODEL OF OPUS 20), MODEL 2ND**Jan 8, 2002  
26 days to decisionK014100 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k014100/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Special                                 |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Dec 13, 2001                            |
| Decision date         | Jan 8, 2002                             |
| Days to decision      | 26 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Opusdent , Ltd.</b>                |
| Location       | Ra&apos;Ananna, IL                    |
| Contact        | ARAVA HACOHEN                         |
| 510(k) history | 5 submissions · 5 cleared · 2000-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k014100/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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