

**K192539 Deka Luxea**Dec 16, 2019  
91 days to decisionK192539 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192539/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Sep 16, 2019                            |
| Decision date         | Dec 16, 2019                            |
| Days to decision      | 91 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>El.En Electronic Engineering Spa</b> |
| Location       | Calenzano, IT                           |
| Contact        | Paolo Peruzzi                           |
| 510(k) history | 27 submissions · 27 cleared · 2007-2023 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192539/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026