

**K895581 MODEL: IR205 ARTICULATED SURGICAL LASER**Dec 13, 1989  
89 days to decisionK895581 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k895581/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Sep 15, 1989                            |
| Decision date         | Dec 13, 1989                            |
| Days to decision      | 89 days                                 |
| Third-party review    | No                                      |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Niic U.S.A., Inc.</b>                |
| Location       | Redwood City, CA, US                    |
| Contact        | JUN NISHIMURA                           |
| 510(k) history | 16 submissions · 16 cleared · 1988-1990 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k895581/>; 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 July 2, 2026