

**K040005 PROFILE 2000/3000 LASER SYSTEM**Mar 29, 2004  
87 days to decisionK040005 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k040005/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 2, 2004
Decision date	Mar 29, 2004
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sciton, Inc</b>
Location	Palo Alto, CA, US
Contact	JAY M PATEL
510(k) history	23 submissions · 23 cleared · 2000-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040005/> 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 31, 2026