

**K945228 125MM HANDPIECE**Mar 20, 1995  
145 days to decisionK945228 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k945228/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 26, 1994
Decision date	Mar 20, 1995
Days to decision	145 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Plc Medical Systems, Inc.</b>
Location	Milford, MA, US
Contact	LISA A ARES
510(k) history	3 submissions · 3 cleared · 1995-1995

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945228/> 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 6, 2026