

**K921807 ULTRALINE STERILE DISPOSABLE FIBER**Jun 18, 1992  
64 days to decisionK921807 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k921807/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 15, 1992
Decision date	Jun 18, 1992
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Heraeus Lasersonics, Inc.</b>
Location	Santa Clara, CA, US
Contact	ROBERT MILDER
510(k) history	38 submissions · 38 cleared · 1988-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k921807/> 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 June 30, 2026