

**K864386 LUXTEC LOUPES FOR SURGICAL VISION**Nov 17, 1986  
12 days to decisionK864386 · Product code: **FSP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k864386/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Loupe, Diagnostic/surgical (FSP)
Date received	Nov 5, 1986
Decision date	Nov 17, 1986
Days to decision	12 days
Third-party review	No

**APPLICANT**

---

Company	<b>Luxtec Corp.</b>
Location	Sturbridge, MA, US
Contact	THOMAS WILK
510(k) history	15 submissions · 15 cleared · 1986-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864386/>; 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 21, 2026