

**K050108 SUREFLEX AND ACCUFLEX LASER LITHOTRIPSY
FIBERS**Mar 14, 2005
55 days to decisionK050108 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k050108/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 18, 2005
Decision date	Mar 14, 2005
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Innovaquartz
Location	Phoenix, AZ, US
Contact	STEVE GRIFFIN
510(k) history	2 submissions · 2 cleared · 1999-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050108/> Data sourced from FDA 510(k) public records (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. - Generated July 2, 2026