

**K963991 FSI LAPAROSCOPIC PROBE FOR ALL FSI ULE-
OVERCLAD FF201 FIBERS**Apr 24, 1997
202 days to decisionK963991 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k963991/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 4, 1996
Decision date	Apr 24, 1997
Days to decision	202 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Full Spectrum, Inc.
Location	Ames, IA, US
Contact	GERALD J SHIRK, M.D.
510(k) history	3 submissions · 3 cleared · 1996-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963991/> 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 4, 2026