

**K964482 FLEXIBLE URETEROSCOPE**Jan 24, 1997  
77 days to decisionK964482 · Product code: **FGB** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k964482/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Nov 8, 1996
Decision date	Jan 24, 1997
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Applied Fiberoptics, Inc.</b>
Location	Mchenry, IL, US
Contact	GRAHAM BAILLIE
510(k) history	3 submissions · 3 cleared · 1982-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964482/> 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 1, 2026