

**K003988 UROSCOPE, ARTES MEDICAL, USA**Sep 6, 2001  
254 days to decisionK003988 · Product code: **FAJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k003988/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Dec 26, 2000
Decision date	Sep 6, 2001
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Artes Medical USA, Inc.</b>
Location	San Diego, CA, US
Contact	WILLIAM KIRKPATRICK
510(k) history	1 submissions · 1 cleared · 2001-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003988/> 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