

**K970598 INTEGRATED VISUALIZATION SYSTEM**Mar 12, 1997  
22 days to decisionK970598 · Product code: **FCW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k970598/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Source, Fiberoptic, Routine (FCW)
Date received	Feb 18, 1997
Decision date	Mar 12, 1997
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Urohealth, Inc.</b>
Location	Costa Mesa, CA, US
Contact	RONALD BERGESON
510(k) history	1 submissions · 1 cleared · 1997-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970598/> 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