

**K960503 DANTEC DUET**Sep 16, 1996  
227 days to decisionK960503 · Product code: **FEN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k960503/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Cystometric, Hydraulic (FEN)
Date received	Feb 2, 1996
Decision date	Sep 16, 1996
Days to decision	227 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dantec Medical, Inc.</b>
Location	Mahwah, NJ, US
Contact	ALAN J SCHAEFER
510(k) history	25 submissions · 25 cleared · 1990-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k960503/> 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 May 20, 2026