

**K913169 DANTEC UD 5500 MK2**Jan 23, 1992  
190 days to decisionK913169 · Product code: **FAP** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k913169/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystometric Gas (carbon-dioxide) On Hydraulic Device (FAP)
Date received	Jul 17, 1991
Decision date	Jan 23, 1992
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dantec Medical, Inc.</b>
Location	Mahwah, NJ, US
Contact	RICHARD D MANTHEI
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/k913169/> 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