

**K844503 UROSTRESSTIK DIAGNOSTIC CYSTOMETRY PACK**Jan 2, 1985  
43 days to decisionK844503 · Product code: **FAP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k844503/>**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         | Nov 20, 1984   |
| Decision date         | Jan 2, 1985  |
| Days to decision      | 43 days  |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Epcom Medical Systems, Inc.</b>      |
| Location       | Walker, MI, US                          |
| Contact        | PAUL ULBRICH                            |
| 510(k) history | 13 submissions · 12 cleared · 1981-1991 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k844503/>; 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 21, 2026