

K915443 URODYNAMIC CATHETERFeb 19, 1992
76 days to decisionK915443 · Product code: **FAP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k915443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystometric Gas (carbon-dioxide) On Hydraulic Device (FAP)
Date received	Dec 5, 1991
Decision date	Feb 19, 1992
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Cook Urological, Inc.
Location	Spencer, IN, US
Contact	MICHELLE YOUNG
510(k) history	104 submissions · 102 cleared · 1986-2011

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