

K944391 OM-4 (TENATIVE) URODYNAMIC MEASRUEMENT SYSTEMFeb 7, 1995
151 days to decisionK944391 · Product code: FEN · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k944391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Cystometric, Hydraulic (FEN)
Date received	Sep 9, 1994
Decision date	Feb 7, 1995
Days to decision	151 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Surgitek
Location	Mchenry, IL, US
Contact	BRIAN KUNST
510(k) history	29 submissions · 28 cleared · 1983-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944391/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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