

K833628 LUMEN-4 URODYNAMIC CATHETERNov 28, 1983
45 days to decisionK833628 · Product code: **FAP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k833628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystometric Gas (carbon-dioxide) On Hydraulic Device (FAP)
Date received	Oct 14, 1983
Decision date	Nov 28, 1983
Days to decision	45 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k833628/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026