

# K243052 Glean Urodynamics System Male Delivery System (GUS-1000-M)

Mar 24, 2025  
178 days to decision

K243052 · Product code: **EXQ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k243052/>

## SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystometer, Electrical Recording (EXQ)
Date received	Sep 27, 2024
Decision date	Mar 24, 2025
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Glean Urodynamics System Female Delivery System (GUS-1000-F); Glean Urodynamics System Uroflowmeter (UFM-1000 (Uroflowmeter))

## APPLICANT

Company	<b>Bright Uro, Inc.</b>
Location	Irvine, CA, US
Contact	Dr. Roychowdhury Suranjan
510(k) history	2 submissions · 2 cleared · 2025-2026

## CLINICAL EVIDENCE - NCT05959655

### Modern Urodynamics System Efficacy (MUSE) Study

Status	Completed
Enrollment	38 patients (actual)
Study sites	5 sites
Condition studied	Urologic Diseases; Urodynamics
Primary purpose	Device_feasibility
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Apr 18, 2024
Sponsor	Bright Uro (Industry)

### Primary outcome

Percentage of Participants With Insertion Success

### Secondary outcome

Percentage of Participants Rating Overall Comfort of Glean Urodynamics as Comfortable or Extremely Comfortable

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT05959655](https://clinicaltrials.gov/study/NCT05959655)