

**K253537 Glean Urodynamics System Male Delivery System  
(GUS-1000-M)**Apr 16, 2026  
154 days to decisionK253537 · Product code: **EXQ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k253537/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystometer, Electrical Recording (EXQ)
Date received	Nov 13, 2025
Decision date	Apr 16, 2026
Days to decision	154 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)); Glean Urodynamics System Abdominal Sensor (GUS-1000-A)

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253537/> 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 13, 2026