April 16, 2026

Bright Uro, Inc.
Suranjan Roychowdhury, Ph.D., RAC
Chief Product Development Officer
3 Goddard
Irvine, CA 92618

Re: K253537
Trade/Device Name: Glean Urodynamics System Male Delivery System (GUS-1000-M); Glean Urodynamics System Female Delivery System (GUS-1000-F); Glean Urodynamics System Uroflowmeter (UFM-1000 (Uroflowmeter)); Glean Urodynamics System Abdominal Sensor (GUS-1000-A)
Regulation Number: 21 CFR§ 876.1620
Regulation Name: Urodynamics Measurement System
Regulatory Class: II
Product Code: EXQ, EXY
Dated: November 18, 2025
Received: November 18, 2025

Dear Suranjan Roychowdhury:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Negeen Haghighi -S

for
Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253537

Please provide the device trade name(s).

Glean Urodynamics System Male Delivery System (GUS-1000-M);
Glean Urodynamics System Female Delivery System (GUS-1000-F);
Glean Urodynamics System Uroflowmeter (UFM-1000 (Uroflowmeter));
Glean Urodynamics System Abdominal Sensor (GUS-1000-A)

Please provide your Indications for Use below.

The Glean Urodynamics System is a urodynamics analyzer system that is intended to quantify the pressure and flow characteristics of the lower urinary tract. The system can be used in adult patients only to perform standard urodynamic tests such as Uroflow, Cystometrogram (CMG), Urethral Pressure Profile (UPP) and Micturition Studies.

The major application of urodynamics is the diagnosis of uncontrolled loss of urine (incontinence), abnormal urinary retention, or neurological cases of micturition disorder. The system is intended to be used as medical diagnostic equipment.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

1. Submitter Information

510 (k) submitter:	Bright Uro, Inc.
Address:	3 Goddard Irvine, CA 92618, United States
Applicant Contact Person:	Dr. Suranjan Roychowdhury Chief Product Development Officer Phone: 949-216-0873 Email : suranjan@brighturo.com
Preparation date:	April 15, 2026

2. Device Name

Trade Name of the Device:	Glean Urodynamics System Male Delivery System (GUS-1000-M); Glean Urodynamics System Female Delivery System (GUS-1000-F); Glean Urodynamics System Uroflowmeter (UFM-1000 (Uroflowmeter)); Abdominal Sensor (GUS-1000-A)
Common Name:	Urodynamics measurement system
Classification Name:	Cystometer, Electrical Recording
Classification Regulation:	21 CFR 876.1620
Device Class:	II
Panel:	Gastroenterology/Urology
Product Code:	EXQ, EXY

3. Predicate Devices

	510(k)#	Trade Name
Primary Predicate	K243052	Glean Urodynamics System
Secondary Predicate	510(k) Exempt	Laborie Goby System

The predicate devices have not been subject to a design related recall.
No reference devices were used in this submission.

4. Device Description

The subject device is a modified Glean Urodynamics System. The specific modification to the subject device consists of adding an Abdominal Sensor component (GUS-1000-A) to the system. The Abdominal Sensor

measures abdominal pressure and enables detrusor pressure to be calculated using the Glean Urodynamics System (GUS) to conduct multi-channel urodynamics studies. Addition of the Abdominal Sensor component enables the subject device to perform multi-channel urodynamics studies. The modified Glean Urodynamics System (GUS) is a multi-channel urodynamic system indicated for standard Urodynamic tests such as Uroflow (UF), Cystometrogram (CMG), Urethral Pressure Profile (UPP), and Micturition Studies (MS).

The Glean Urodynamics System obtained market clearance through the original 510(k) Premarket Notification K243052. No changes were made to the intended use, indications for use, or technological characteristics of the predicate device's three physical components, the Bladder Sensor, Insertion Tool, and Uroflowmeter. The Glean Mobile App (Clinician) and Glean Web App software were modified to include use with the Abdominal Sensor. The Glean Mobile App (Patient) was not modified.

The multi-channel GUS consists of four physical component elements: Bladder Sensor, Abdominal Sensor, Insertion Tool, and Uroflowmeter, as well as three software applications: Glean Mobile App (Clinician), Glean Mobile App (Patient), and Glean Web App. The patient may use the Glean Mobile App as a digital voiding diary, logging fluid input, leakage, urgency, and other urological symptoms. The clinician may use the Glean Mobile App to prepare the Sensor for insertion, log symptoms, and download data. The Glean Web App may be used by clinicians to view and analyze data.

The Bladder Sensor is inserted through the urethra into the bladder using the Insertion Tool. Once inserted, the Sensor has a Removal String that hangs out of the urethra to enable removal of the Sensor. The Sensor may stay in the bladder for the entire duration of monitoring while collecting data. The Sensor stores data that may be wirelessly transmitted to the Glean Mobile App (Clinician) once it is removed from the body.

The Abdominal Sensor is manually inserted into the anorectal canal. Once inserted, the Abdominal Sensor has a removal string that extends from the anus to enable removal of the Sensor. The Sensor may stay in the rectum for the entire duration of monitoring while collecting data. The Sensor stores data that may be wirelessly transmitted to the Glean Mobile App used by the clinician once it is removed from the body.

The Uroflowmeter is used to measure voided volume and flow. The Glean Mobile App (Clinician) wirelessly receives data from the Uroflowmeter after the patient has completed a voiding cycle.

5. Indications For Use

The Glean Urodynamics System is a urodynamics analyzer system that is intended to quantify the pressure and flow characteristics of the lower-urinary tract. The system can be used in adult patients only to perform standard urodynamic tests such as Uroflow, Cystometrogram (CMG), Urethral Pressure Profile (UPP) and Micturition Studies.

The major application of urodynamics is the diagnosis of uncontrolled loss of urine (incontinence), abnormal urinary retention, or neurological cases of micturition disorder. The system is intended to be used as medical diagnostic equipment.

6. Comparison of Technological Characteristics with Predicate Device

Technological/ Performance Characteristics	Subject Device	Primary Predicate Device	Secondary Predicate Device
	Glean Urodynamic System with Abdominal Sensor	**Glean Urodynamic System**	**Laborie Goby System (Exempt)**
Intended Use / Indications for Use	The Glean Urodynamics System is a urodynamic analyzer system that is intended to quantify the pressure and flow characteristics of the lower-urinary tract. The system can be used in adult patients only to perform standard urodynamic tests such as Uroflow, Cystometrogram (CMG), Urethral Pressure Profile (UPP) and Micturition Studies. The major application of urodynamics is the diagnosis of uncontrolled loss of urine (incontinence), abnormal urinary retention, or neurological cases of micturition disorder. The system is intended to be used as medical diagnostic equipment.	The Glean Urodynamics System is a urodynamic analyzer system that is intended to quantify the pressure and flow characteristics of the lower-urinary tract. The system can be used in adult patients only to perform standard urodynamic tests such as Uroflow, Cystometrogram (CMG), Urethral Pressure Profile (UPP) and Micturition Studies. The major application of urodynamics is the diagnosis of uncontrolled loss of urine (incontinence), abnormal urinary retention, or neurological cases of micturition disorder. The system is intended to be used as medical diagnostic equipment.	The Goby™ system is a Urodynamic Analyzer system that is intended to quantify the pressure, flow, and EMG characteristics of the lower urinary tract. Using the available transducers, the system can be used for performing standard Urodynamic tests such as Uroflow, CMG, UPP, and Micturition Studies. The major application of Urodynamics is the diagnosis of uncontrolled loss of urine (incontinence), abnormal urinary retention, or neurological cases of Micturition disorder. The device is intended to be used as medical diagnostic equipment.
Principles of Operation	An electronic pressure sensor is used to measure pressure in the bladder and in the abdomen. This sensor is connected to an electrical recording device that stores measurements from the sensor. Once monitoring is complete, the sensor is removed from the patient's body, measurements are transferred from the sensor to a tablet, and the sensor discarded.	An electronic pressure sensor is used to measure pressure in the bladder. This sensor is connected to an electrical recording device that stores measurements from the sensor. Once monitoring is complete, the sensor is removed from the patient's body, measurements are transferred from the sensor to a tablet, and the sensor discarded.	A catheter is used to measure pressure in the bladder and in the abdomen. The catheter is connected to a sensor outside the patient. The sensor is connected to an electrical recording device that stores measurements from the sensor. Once monitoring is complete, the catheter is removed from the patient's body and discarded.
Anatomical location of use	The silicone housing with sensor and electronics are placed in the patient's bladder and anorectal cavity.	The silicone housing with sensor and electronics are placed in the patient's bladder.	The catheter tip is positioned in the bladder and anorectal cavity. The proximal portion of the catheter is taped to the patient's body.
Mode of Operation	Continuous	Continuous	Continuous
Pressure (Range)	0 to 320 cm H2O	0 to 320 cm H2O	0 to 320 cm H20 (PLM001) -50 to 200 cm H2O (COM762)
Pressure Sampling Rate	20 Hz (minimum rate)	20 Hz	20 Hz
Sensor/Catheter diameter	Less than 5.35 mm or 16 Fr (bladder) 17.5 mm maximum (abdominal)	Less than 5.35 mm or 16 Fr (bladder)	7 Fr (bladder) 7 Fr (abdominal)
Sensor/ Catheter Material	Silicone	Silicone	TPU-PVD
Environment of Use	Clinic	Clinic	Clinic
Enables ambulatory urodynamic	Yes	Yes	Yes

Technological/ Performance Characteristics	Subject Device	Primary Predicate Device	Secondary Predicate Device
	Glean Urodynamic System with Abdominal Sensor	**Glean Urodynamic System**	**Laborie Goby System (Exempt)**
monitoring			
Single Use Sensor/ Catheter	Yes	Yes	Yes
Method of Removal	String	String	Catheter
Integrated EMG	Yes	Yes	Yes
Integrated Uroflowmetry	Yes	Yes	Yes

As evidenced by the above table, both the subject and the predicate devices have the same intended use, but the subject and predicate devices have different technological characteristics. Additionally, several types of performance testing were conducted on the subject device to evaluate its safety and effectiveness. Overall, it was established that the differences in technological characteristics between the subject and the predicate devices do not raise different questions of safety or effectiveness.

7. Non-Clinical Testing

Below is a list of the evaluations and tests that were performed and successfully completed for the subject device per the specified guidance and standards:

- Biocompatibility evaluation according to ISO 10993-1:2018 - *Biological evaluation of medical devices* — Part 1: Evaluation and testing within a risk management process and FDA Guidance "*Use of International Standard ISO 10993-1*" (2016).

- Electrical Safety testing according to IEC 60601-1: 2020 - *Medical electrical equipment – Basic safety and essential performance*

- Electromagnetic Compatibility testing according to IEC 60601-1-2: 2020 - *General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests*

- Software Verification and Validation Testing according to FDA's Guidance "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*"

- Cybersecurity risk management activities according to FDA Guidance *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, issued September 27, 2023*

- Human Factors Engineering/Usability Engineering (HFE/UE) processes were used as part of the design and development process for the subject device according to FDA Guidance, "*Applying Human Factors and Usability Engineering to Medical Devices"*

- Packaging testing according to ISO 11607-1:2019/Amd. 1:2023- *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including Amendment 1 (2023)]* and Shelf Life testing

- Bioburden (for abdominal sensor only): USP <62> *Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms*

Additionally, battery service life and performance verification test data were submitted to establish performance and durability of the subject device.

All pre-determined acceptance criteria were met.

8. Conclusions

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate devices.