



March 24, 2025

Bright Uro, Inc.
Dr. Roychowdhury Suranjan
Chief Product Development Officer
3 Goddard
Irvine, California 92618

Re: K243052
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))
Regulation Number: 21 CFR 876.1620
Regulation Name: Urodynamics Measurement System
Regulatory Class: II
Product Code: EXQ, EXY
Dated: September 26, 2024

Dear Dr. Roychowdhury Suranjan:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Jessica K. Nguyen -S

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

510(k) Number (if known)

K243052

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))

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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: March 24, 2025

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))

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 and Reference Devices

	510(k)#	Trade Name
Predicate	510(k) Exempt	Laborie Goby System
Reference	K960503	Dantec Duet

The predicate and reference devices have not been subject to a design related recall.

4. Device Description

The Glean Urodynamics System (GUS) is a single-channel urodynamic system indicated for standard Urodynamic tests such as Uroflow (UF), Cystometrogram (CMG), Urethral Pressure Profile (UPP), and Micturition Studies (MS).

GUS consists of the following three physical component elements: Sensor, Insertion Tool, and

Uroflowmeter, as well as the following 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 Sensor can be 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 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 the Technological Characteristics with Predicate Device

Technological/ Performance Characteristics	K243052- Bright Uro Glean™ (Subject Device)	Laborie Goby™ (Predicate Device)
Indication 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.	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. 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. 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	The silicone housing with sensor and	The catheter tip positioned in bladder and

location of use	electronics are placed in the patient's bladder.	proximal portion of catheter is taped to patient's body.
Mode of operation	Continuous	Continuous
Pressure (Range)	0 to 320 cm H ₂ O	0 to 320 cm H ₂ O (PLM001) -50 to 200 cm H ₂ O (COM762)
Pressure (Sampling Rate)	20 Hz	20 Hz
Sensor/Catheter diameter	Less than 5.35 mm or 16 Fr	8 Fr
Sensor/Catheter Material	Silicone	TPU-PVC
Environment of Use	Clinic	Clinic
Enables ambulatory urodynamic monitoring	Yes	Yes
Single Use Sensor/Catheter	Yes	Yes
Method of Removal	String	Catheter
Integrated EMG	No	Yes
Integrated Uroflowmetry	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. The reference device was used to support the use of an electronic pressure sensor in the subject device. 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 does not raise different questions of safety or effectiveness.

7. Non-Clinical Testing

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

- Biocompatibility testing 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*”
- Sterilization validation was performed according to ISO 11135: 2014- *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices* and FDA guidance document “*Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices*

Labeled as Sterile”

- 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) testing according to FDA Guidance, “*Applying Human Factors and Usability Engineering to Medical Devices*”
- A GLP chronic animal safety study was conducted on sixteen sheep to demonstrate the safety related to the use of the Glean Urodynamic Delivery System for urodynamic monitoring. Results from the GLP animal study demonstrated acceptable device performance during insertion, placement, and removal.

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. Clinical Testing

A prospective, open-label, multi-center, interventional study was conducted to evaluate the feasibility, efficacy, and safety of the Glean Urodynamics System for use in the clinics to collect vesical pressure.

Adult male and female patients with lower urinary tract dysfunction (LUTD) who were recommended or scheduled for conventional urodynamics (UDS) were eligible. Patients were excluded if they were pregnant or breastfeeding, or pregnant within the past 6 months; if they intended to become pregnant during the study period; had a symptomatic urinary tract infection (UTI); were unable to tolerate 18 French (Fr) catheterization; were unable to provide informed consent; and those who, at the clinician’s determination, would not be appropriate for the study.

Participants underwent standard of care conventional UDS followed by intravesical insertion of the Glean sensor. After Glean insertion, participants were asked to perform a series of maneuvers (e.g., cough) and then the bladder was allowed to fill naturally. Upon participant-reported strong desire to void, pressure-flow studies were recorded using the indwelling Glean sensor and standard uroflowmetry. Post-void residuals were then measured followed by removal of the Glean sensor. Participants completed comfort and preference questionnaires after removal of the Glean sensor. Participants were followed up within 7-14 days to assess the incidence of adverse events.

Thirty-eight participants were enrolled, 34 were prepared to undergo Glean UDS, and insertion was attempted in only 33 participants (i.e., the Glean delivery system contacted the participant’s urethral tissue). The device was not available for insertion in one participant due to a device failure prior to the insertion attempt. There was one failed insertion attempt in a male participant where a subsequent cystoscopic examination determined the presence of a bladder neck contracture which likely prevented the advancement of the Glean device for sensor placement in the bladder. Thus, 32 of the 33 attempted insertions were successful as either having their placement confirmed with the passage of urine through the insertion sheath or through clinician confirmation. Overall, 32 (84.2%) of the 38 enrolled participants underwent Glean UDS.

The median age of the 32 participants who underwent Glean UDS was 61.0 years (range, 25 to 79) and approximately half were male (53.1%). The median insertion time of the Glean sensor was 33.62 seconds (range, 12.32 to 256). All 32 participants were able to void with the Glean sensor indwelling. The Glean Urodynamics System successfully recorded vesical pressure data during the in-clinic ambulatory session in

all 32 participants who underwent UDS assessments using the Glean system. The removal of the Glean sensor was successful in 100 percent of participants who had Glean UDS (n=32). . Eighty-one percent of Glean sensor insertions were rated as easy or very easy by clinicians and 97 percent of Glean sensor removals were rated as easy or very easy by clinicians. Patient feedback regarding insertion comfort was comparable between the Glean sensor and conventional UDS catheters. Patients reported higher rates of discomfort with placement of the Glean device, but when asked their preference for type of UDS testing in the future, more subjects (64.5%) preferred the subject device over conventional UDS. The higher amount of discomfort during the removal of the Glean device may be due to every participant having the Glean device used after they went through the conventional UDS procedure.

Clinicians interpreted the Glean UDS results of the 32 participants who underwent Glean urodynamics assessments and confirmed the initial diagnosis in eight (25.0%) and changed or refined the initial diagnosis in 21 (65.6%) including two (6.3%) participants whose Glean results were inconclusive and seven (21.9%) where an incontinence diagnosis was not specifically confirmed by the investigators due to missing leakage annotations during Glean UDS; data from the clinician interpretation was unavailable for three (9.4%) participants. In comparison, the clinician's interpretation of the conventional UDS results confirmed the initial diagnosis in 24 (75.0%) participants and changed or refined the initial diagnosis in eight (25.0%). Based on clinician interpretation of UDS outcomes, the Glean UDS was able to diagnose different urological conditions (e.g., OAB, underactive bladder, incomplete emptying of the bladder etc.) accurately in the study subjects. However, urinary incontinence conditions were not accurately diagnosed due to the missing leak annotations on the Glean UDS tracing. .

There were 14 adverse events in 12 participants: nine events of gross hematuria (in nine participants), two events of dysuria (in two participants), two events of genitourinary pain or discomfort (in two participants), and one event of asymptomatic bacteriuria (in one participant). No serious adverse events were reported. Seven of the adverse events (in seven participants) were attributed to the Glean Urodynamics System including mild gross hematuria (four events), mild genitourinary discomfort (two events), and mild dysuria (one event). Four of the adverse events (in four participants) were attributed to conventional UDS; all four events were gross hematuria. Device-related adverse events self-resolved without intervention by follow-up.

In conclusion, the clinical data submitted on the subject device demonstrated effective diagnostic performance for various urological conditions, comparable to conventional urodynamic systems, with a similar safety profile. While it did not provide a diagnosis for urinary incontinence due to missing patient annotations, its accuracy in diagnosing other urological conditions supported its reliability. Information related to the importance of capturing accurate patient annotations regarding the occurrences of incontinence episodes is included on the labeling.

9. Conclusions

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