March 12, 2026

Prodeon Medical, Inc.
Elaine Aplaon
Sr. Manager, Regulatory Affairs
452 Oakmead Pkwy.
Sunnyvale, California 94085

Re: K253525
Trade/Device Name: Urocross Expander System (Model Numbers ES2018 and ES3025)
Regulation Number: 21 CFR 876.5510
Regulation Name: Temporarily-Placed Urethral Opening System For Symptoms of Benign Prostatic Hyperplasia
Regulatory Class: II
Product Code: QKA
Dated: February 6, 2026
Received: February 9, 2026

Dear Elaine Aplaon:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

MARK J. ANTONINO -S

Mark J. Antonino, M.S.
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. | K253525 |

Please provide the device trade name(s).

Urocross Expander System (Model Numbers ES2018 and ES3025)

Please provide your Indications for Use below.

The Urocross Expander System is intended to relieve urinary outflow obstruction. The Urocross Expander System is indicated for the treatment of lower urinary tract symptoms (LUTS) attributed to benign prostatic hyperplasia (BPH) in men ≥ 45 years old.

The Urocross Expander Implant is indicated for an indwell duration of up to 6 months.

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

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**K253525**

**510(k) SUMMARY**

**Urocross Expander System**

## Contact Details

| | |
|---|---|
| **Applicant Name:** | Prodeon Medical, Inc. |
| **Applicant Address:** | 452 Oakmead Parkway<br>Sunnyvale, CA 94085<br>United States |
| **Applicant Contact Telephone:** | +1 669-467-1100 |
| **Applicant Contact:** | Elaine Aplaon |
| **Applicant Contact Email:** | elaine.aplaon@prodeonmedical.com |
| **Date Prepared:** | 12 March 2026 |

## Device Name

| | |
|---|---|
| **Device Trade Name** | Urocross Expander System |
| **Common Name:** | Temporary Implanted Prostatic Device |
| **Classification Name** | Temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia |
| **Regulation Number:** | 21 CFR 876.5510 |
| **Product Code(s)** | QKA |
| **Predicate Device:** | DEN190020 – iTind System |

## Device Description

The Urocross Expander System is a temporary implantable urethral opening system. The Urocross Expander System consists of a sterile, single-use nitinol tissue expander (Urocross Expander Implant) preloaded in a catheter delivery system. The delivery system is made of biocompatible materials widely used in the manufacture of medical devices such as Pebax, stainless steel, polycarbonate, PTFE, PEEK, and nylon. The Urocross Expander System is

designed to be advanced through the instrument channel (central through lumen) of a commercially available flexible cystoscope. The Urocross Expander Implant is then delivered and deployed under cystoscopic visualization in the prostatic urethra. Once deployed in the target location, the expansive strength and stiffness of the Urocross Expander Implant push the lateral lobes apart, increasing the opening of the prostatic urethra lumen, thereby improving urine flow and providing relief from LUTS.

The Urocross Expander Implant is available in two sizes, small (20 mm length x 18 mm diameter, Model Number ES2018) and large (30 mm length x 25 mm diameter, Model Number ES3025). The small size is intended for prostatic urethral lengths of 25-45 mm, and the large size is intended for prostatic urethral lengths of 40 - 60 mm. The Urocross Expander Implant is designed to be in situ for up to 6 months and retrieved any time during the in-dwell period. Retrieval may be done using the Prodeon Urethral Sheath System and commercially available compatible cystoscopes and graspers commonly used during urological procedures.

**Intended Use/Indications for Use**

The Urocross Expander System is intended to relieve urinary outflow obstruction. The Urocross Expander System is indicated for the treatment of lower urinary tract symptoms (LUTS) attributed to benign prostatic hyperplasia (BPH) in men ≥ 45 years old.

The Urocross Expander Implant is indicated for an indwell duration of up to 6 months.

**Indications for Use Comparison**

The indications for use are not the same but substantially equivalent. The minor differences in wording and age group (45 and older vs 50 and older) do not raise new questions of safety and effectiveness as both the predicate and subject device relieve urinary outflow obstruction as demonstrated by the clinical performance testing.

**Technological Comparison**

| Urocross Expander System (Subject Device) | iTind System (Predicate Device) |
|---|---|
| Temporary nitinol implant for treatment of lower urinary tract symptoms attributed to BPH in men ≥ 45 years old. | Temporary nitinol implant for treatment of symptoms due to urinary outflow obstruction secondary to BPH in men age 50 and above. |
| Indwell up to 6 months. | Indwell of 5-7 days. |
| Mechanism of Action: Expand to create an opening in the prostatic urethra through which urine can flow. | Mechanism of Action: Expand to create an opening in the prostatic urethra through which urine can flow. |
| Deployment Mechanism: Push mechanism to deploy the implant in the prostatic urethra. | Deployment Mechanism: Push mechanism to deploy using a guidewire. |
| Implant Material: Nitinol | Implant Material: Nitinol, polyester suture |

| Urocross Expander System (Subject Device) | iTind System (Predicate Device) |
|---|---|
| Delivery System: Flexible catheter and handle | Delivery System: Introducer sheath, anchoring leaflet, and guidewire |
| Delivery System Materials:<br>Flexible Catheter: Biocompatible materials widely used in the medical device industry<br>Handle: Biocompatible materials widely used in the medical device industry | Delivery System Materials:<br>Introducer Sheath: Biocompatible materials widely used in the medical device industry<br>Anchoring Leaflet: Biocompatible materials widely used in the medical device industry |
| Removal: Retrieved using Prodeon Urethral Sheath System and commercially available flexible cystoscopes and graspers. Alternatively, the Urocross Expander Implant can be removed using commercially available rigid cystoscopes. | Removal: The iTind implant is tretrieved using the retrieval kit (snare), an open-ended Foley catheter, and an access sheath. |
| Provided sterile, for single use only. | Provided sterile, for single use only |
| Sterilized by EtO. | Sterilized by EtO. |
| Biocompatible per ISO 10993-1 | Biocompatible per ISO 10993-1 |
| MR Conditional | MR Conditional |

Both the predicate and the subject device, the Urocross Expander System, share substantially equivalent technological characteristics. Both devices are temporary implants that relieve lower urinary tract symptoms by mechanically creating a channel. Both devices are comparable in their design/material (both are composed of nitinol with delivery systems made from biocompatible materials widely used in the medical device industry). Both the predicate and subject device are designed to expand to create an opening in the prostatic urethra through which urine can flow. Both devices are delivered to the intended location through a cystoscope inserted through the penile orifice. Both devices are temporarily placed in the prostatic urethra (5-7 days for the predicate device vs 6 months for the subject device) after which the implants must be removed. Both devices are for single use only and sterilized with EtO. The differences between the subject device and the predicate device do not alter the suitability of the subject device for its intended use.

The predicate device has not been subject to a recall.

**Non-Clinical and/or Clinical Tests Summary & Conclusions**

The following bench testing data was provided in support of the substantial equivalence determination:

General performance testing, including:

Dimensional (ID, OD, Length)

Irrigation (references: ISO 10555-1: 2013 and ISO 20696:2018)

Luer compatibility

Trackability/kink

Deployment (Force and Accuracy)

Tensile Strength (references: ISO 10555-1: 2013 and ISO 20696:2018)

Leak test

Implant Radial Force

Catheter Integrity

Corrosion Testing per ASTM F2129-19a and ASTM F2129-24

MR Compatibility per ASTM F2182-11a, ASTM F2052-15, ASTM F2213-17, and ASTM F2219-13

Finite Element Analysis (FEA)

Shelf-life testing to support up to 25 months shelf-life per ASTM F1980-16, ASTM F1886/ F1886M-16, ASTM F2096-11, and ASTM F88/F88M-15

The following Biocompatibility testing was performed:

- Cytotoxicity per ISO 10993-5:2009
- Sensitization per ISO 10993-10:2010
- Irritation per ISO 10993-10:2010
- Material-Mediated Pyrogenicity per ISO 10993-11 and USP <151>
- Implantation per ISO 10993-6:2016
- Chemical characterization per ISO 10993-18:2020
- Toxicological Risk Assessment per ISO 10993-17:2002

Based on the totality of evidence, including the biocompatibility testing, chemical characterization and extraction studies, corrosion testing, post explant data, and clinical study results, the Urocross Expander System has an acceptable biocompatibility profile and is substantially equivalent to the predicate device.

Sterilization by ethylene oxide has been validated for the Urocross Expander System in accordance with ISO 11135:2014.

Non-clinical test results demonstrate that the Urocross Expander System meets all predetermined mechanical and functional requirements. Testing performed is appropriate for the design of the Urocross Expander System and similar to the testing performed on the predicate device. The Urocross Expander System is biocompatible and meets the MR conditional rating. Corrosion testing shows that the Urocross Expander Implant is resistant to corrosion and unlikely to undergo pitting corrosion *in vivo*. Based on the results of the testing, the Urocross Expander System is substantially equivalent to the predicate device.

Clinical Study Summary

The Expander-2 Pivotal Trial was an FDA-approved Investigational Device Exemption (IDE) study, designed to demonstrate the safety and efficacy of the Urocross Expander System/Retrieval Sheath and the procedure to treat patients with symptomatic BPH.

The Expander-2 study was designed as a prospective, randomized, blinded, multi-center sham study of up to 240 male subjects (160 Urocross arm subjects: 80 Sham subjects), aged 45 years or older, suffering from moderate to severe LUTS (IPSS ≥13). The primary efficacy endpoint objective was to achieve greater than 25% improvement in total IPSS from baseline (pre-treatment) through 3 months post procedure when compared to the sham arm. The primary safety endpoint was the rate of extended post-operative urinary catheterization lasting more than 7 days from treatment for inability to void. Secondary endpoints evaluated at each follow up assessed the treatment effect (IPSS) through 3.5 years post implant (3 years post retrieval), Quality of Life (QoL), uroflow (Qmax/PVR), incontinence (M-ISI score), impact on sexual function (MSHQ, IIEF), and procedural tolerability (VAS score).

The study randomized 240 men at 18 centers in the United States and 5 centers in Canada. The average age of the subjects was 66.0 years. The average IPSS at baseline was 24.6.

The Urocross Expander System exhibited a device- and/or procedure-related urological AE rate of 36.9% for the Urocross implantation procedure and 18.8% for the retrieval procedure. No serious adverse events were reported for the ITT population. The sexual function and continence scores were not adversely affected by either the implant or retrieval procedures. The primary safety endpoint was the rate of extended post-operative urinary catheterization (> 7 days) from treatment for inability to void, which occurred in 3.1% of the Urocross arm subjects(n=5).

**CEC-Adjudicated Device/Procedure Related Urological AEs - Urocross Arm**

| Type of Event by MedDRA PT | Urocross Arm | |
|---|---|---|
| | Events N=211 | Subjects N=160 |
| Micturition urgency | 14.7% (31) | 18.8% (30) |
| Dysuria | 12.3% (26) | 15% (24) |
| Hematuria/haematospermia/hemorrhage of urinary tract | 12.3% (26) | 14.4% (23) |
| Painful ejaculation / Ejaculation Disorder/Ejaculation Failure/Retrograde Ejaculation | 9.0% (19) | 11.3% (18) |
| Pollakiuria | 9.5% (20) | 11.0% (19) |
| Urinary retention | 9.0% (19) | 10.6% (17) |
| Urinary tract infection (UTI) | 6.6% (14) | 7.5% (12) |
| Groin pain/scrotal pain/perineal and testicular pain/ suprapubic pressure/pelvic pain and discomfort | 5.2% (11) | 6.3% (10) |
| Nocturia | 5.2% (11) | 6.9% (11) |
| Urge incontinence | 3.8% (8) | 5.0% (8) |

| Type of Event by MedDRA PT | Urocross Arm | |
|---|---|---|
| | Events N=211 | Subjects N=160 |
| Urine flow decreased | 2.4% (5) | 3.1% (5) |
| Erectile Dysfunction/ Sexual dysfunction | 1.9% (4) | 2.5% (4) |
| Hypertonic Bladder | 1.4% (3) | 1.9% (3) |
| Bladder spasms | 0.9% (2) | 1.3% (2) |
| Urinary hesitation | 0.9% (2) | 1.3% (2) |
| Balanoposthitis | 0.9% (2) | 1.3% (2) |
| Epididymitis | 0.5% (1) | 0.6% (1) |
| Urethral Meatus Stenosis | 0.5% (1) | 0.6% (1) |
| Bladder Diverticulum | 0.5% (1) | 0.6% (1) |
| Urethral discharge | 0.5% (1) | 0.6% (1) |
| Varicocele | 0.5% (1) | 0.6% (1) |
| Nephrolithiasis | 0.5% (1) | 0.6% (1) |
| Loss of Libido | 0.5% (1) | 0.6% (1) |
| Urethritis noninfective | 0.5% (1) | 0.6% (1) |

Adjustment within Prostatic Urethra

In seventeen (17) or 10.6% of the Expander arm subjects, the treating physician adjusted the Urocross implant following initial placement within the prostatic urethra. The decision to adjust the implant was at discretion of the treating urologist. None of the subjects experienced a serious device/procedure related adverse event.

Reposition from the bladder

In nine (9) or 5.6% of the Expander arm subjects, the Urocross Delivery System was placed too close to the internal sphincter, resulting in the Urocross implant deploying into the bladder. In 7 of the 9 subjects, the implant was retracted from the bladder using a urological grasper and repositioned within the prostatic urethra. In 2 of 9 subjects, the implant was retrieved from the bladder and removed from the subject using a sheath and grasper. Following implant removal, during the same procedure, a second Urocross implant was placed in the prostatic urethra. None of the subjects experienced a device/procedure related serious adverse event.

Migration and Retrieval

Two (2) or 1.2% of the Expander arm subjects experienced acute migration of the Urocross implant into the bladder, and the implant was removed. Neither subject underwent a subsequent Urocross. None of the subjects experienced a device/procedure related serious adverse event.

Migration Post Implantation Procedure

In the Expander arm, the post-implantation procedure migration rate was 1.9% (3/160. Neither subject experienced a device/procedure related serious adverse event.

The Expander-2 clinical results demonstrated that the Urocross group showed an average improvement of 6.5 points from baseline at the 3-month post-treatment time point, compared to 5.9 points for the sham group, which provided symptom relief but did not meet the pre-specified primary efficacy endpoint at 3 months post treatment.

An exploratory endpoint analysis was performed to determine the average improvement at 7-month (1-month post-retrieval) and 12-month (6-months post-retrieval), with 10.6 points and 11.0 points IPSS improvement from baseline, respectively.

**Special Controls Per 21 CFR 876.5510:**

In combination with the general controls of the FD&C Act, the Urocross Expander System is subject to the following special controls:

1. Clinical performance testing with the device under anticipated conditions of use must evaluate improvement in urinary outflow symptoms and document the adverse event profile.
2. The patient-contacting components of the device must be demonstrated to be biocompatible.
3. Performance data must demonstrate the sterility of the patient-contacting components of the device.
4. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.
5. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
   (i) Deployment and removal; and
   (ii) Mechanical strength.
6. Labeling must include:
   (i) Instructions for use, including the recommended training for safe use of the device;
   (ii) A summary of the clinical performance testing conducted with the device, including device- and procedure-related adverse events; and
   (iii) A shelf life.

Based on the totality of evidence provided, including the clinical study data, biocompatibility testing, sterilization validation, shelf-life testing, performance testing, and labeling, the Urocross Expander System has met the Special Controls requirements and is substantially equivalent to the predicate device.

**Conclusion:**

The nonclinical and clinical testing of the device demonstrates that the Urocross Expander System is as safe and effective as the predicate device and performs as well as or better than the legally marketed predicate devices.