June 22, 2026

Prodeon Medical, Inc.
Elaine Aplaon
Sr. Manager, Regulatory Affairs
2200 Zanker Rd., Unit F
San Jose, California 95131

Re: K261342
Trade/Device Name: Urocross Expander System (UES-2018-C1)
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: April 23, 2026
Received: April 23, 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), 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,

Mark R. Kreitz -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261342

Device Name
Urocross Expander System (Model Number UES-2018-C1)

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K261342

510(k) SUMMARY

Urocross Expander System

Contact Details

Applicant Name:	Prodeon Medical, Inc.
Applicant Address:	2200 Zanker Road Ste F San Jose, CA 95131 United States
Applicant Contact Telephone:	+1 669-467-1100
Applicant Contact:	Elaine Aplaon
Applicant Contact Email:	elaine.aplaon@prodeonmedical.com

Date Prepared:	22 June 2026

Device Name

Device Trade Name	Urocross Expander System (Model Number UES-2018-C1)
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:	K253525 - Urocross Expander 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, polyimide, PTFE, polycarbonate, HDPE, etc. The Urocross Expander System is designed to be

advanced through the instrument channel (central through lumen) of a commercially available flexible or rigid 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 one size, 20 mm length x 18 mm diameter (Model/REF Number UES-2018-C1) which is compatible with prostatic urethral lengths of 25-45 mm. The Urocross Expander Implant is designed to be in situ for up to 6 months and can be retrieved at 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. Alternatively, a rigid cystoscope system and grasper can be used for retrieval.

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 identical to that of the predicate device.

Summary of Technological Characteristics

The Urocross Expander Implant of the subject device is identical to the small Urocross Expander Implant of the predicate device, Model Number ES2018. The Delivery System has been modified for ease of use and ergonomics in the delivery of the Urocross Expander Implant. Both Delivery Systems are comparable in their design/material composition (both are made from biocompatible materials widely used in the medical device industry such as Pebax, stainless steel, polycarbonate, etc.). The subject device Delivery System includes a tether mechanism to control release of the Expander Implant for optimal placement. An Irrigation Connector with Stopcock is included with the subject device Delivery System.

Urocross Expander System (Subject Device)	Urocross Expander System (Predicate Device) - K253525
Temporary nitinol implant for treatment of lower urinary tract symptoms attributed to BPH in men ≥ 45 years old.	Same
Indwell up to 6 months.	Same

Urocross Expander System (Subject Device)	Urocross Expander System (Predicate Device)
Mechanism of Action: Expand to create an opening in the prostatic urethra through which urine can flow.	Same
Deployment Mechanism: Push mechanism to deploy the implant in the prostatic urethra.	Same
Implant Material: Nitinol	Same
Delivery System: Flexible catheter and handle	Delivery System: Flexible catheter and handle
Delivery System Materials: Flexible Catheter: Biocompatible materials widely used in the medical device industry Handle: Biocompatible materials widely used in the medical device industry Includes a tether mechanism to control release of the Expander Implant for optimal placement. Includes a separate Irrigation Connector and Stopcock	Delivery System Materials: Flexible Catheter: Biocompatible materials widely used in the medical device industry Handle: Biocompatible materials widely used in the medical device industry Irrigation connector built into the handle.
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: Same
Provided sterile, for single use only.	Same
Sterilized by EtO.	Same
Biocompatible per ISO 10993-1	Same

Both the predicate and the subject device, the Urocross Expander System Model Number UES-2018-C1, share substantially equivalent technological characteristics. The Expander Implant of the subject device is identical to the small Expander Implant of the predicate device. Both Delivery Systems are comparable in their design/material (both are made from biocompatible materials widely used in the medical device industry). 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 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)
- Irrigation connector compatibility
- Trackability/kink
- Deployment (Force and Accuracy)
- Tensile Strength (references: ISO 10555-1: 2013 and ISO 20696:2018)
- Leak test
- Expander Implant Radial Force
- Catheter Integrity
- Shelf-life testing to support up to 12 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 10993-23:2010

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. Based on the results of the testing, the Urocross Expander System is substantially equivalent to the predicate device.

Conclusion:

The nonclinical testing of the subject device demonstrates that the Urocross Expander System meets its design requirements and is as safe and effective for its intended use. Based on the results of the testing, the Urocross Expander System is substantially equivalent to the predicate device.