



October 7, 2025

Prodeon Medical, Inc.
Elaine Aplao
Sr. Manager, Regulatory Affairs
452 Oakmead Parkway
Sunnyvale, California 94085

Re: K252572
Trade/Device Name: Prodeon Urethral Sheath System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: August 14, 2025
Received: August 14, 2025

Dear Elaine Aplao:

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, 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 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,


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

Indications for Use

510(k) Number (if known)
K252572

Device Name
Prodeon Urethral Sheath System

Indications for Use (Describe)

The Prodeon Urethral Sheath System is used to establish a conduit during endoscopic urological procedures, facilitating the passage of endoscopes and other instruments into the urinary tract. It is designed to establish a conduit for the treatment of urinary stones or other urinary diseases during the endoscopic procedures.

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) #:

510(k) Summary

Prepared on: 2025-08-19

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Prodeon Medical, Inc.
Applicant Address	452 Oakmead Parkway Sunnyvale CA 94085 United States
Applicant Contact Telephone	(669) 467-1100
Applicant Contact	Mrs. Elaine Aplaon
Applicant Contact Email	elaine.aplaon@prodeonmedical.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Prodeon Urethral Sheath System
Common Name	Endoscope and accessories
Classification Name	Endoscopic Access Overtube, Gastroenterology-Urology
Regulation Number	876.1500
Product Code(s)	FED

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K243820	Hoover Negative Pressure Access Sheath (Hoover) (Hoover Model #'s IVX-NS-1040, IVX-NS-1050, IVX-NS-1140, IVX-NS-1150, IVX NS-1240, IVX-NS-1250)	FED

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Prodeon Urethral Sheath System comprises a Sheath and Irrigation Valve. The Prodeon Urethral Sheath System is a sterile, single-use, disposable device made of biocompatible materials with a long history of use in medical devices. The Prodeon Urethral Sheath System is a conduit for facilitating the introduction of endoscopes and other instruments into the urinary tract. The Prodeon Urethral Sheath System includes an Irrigation Valve that attaches to the cystoscope luer and allows the introduction of a tool/instrument and irrigation into the channel of a cystoscope.

The Prodeon Urethral Sheath System is available in one size.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Prodeon Urethral Sheath System is used to establish a conduit during endoscopic urological procedures, facilitating the passage of endoscopes and other instruments into the urinary tract. It is designed to establish a conduit for the treatment of urinary stones or other urinary diseases during the endoscopic procedures.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The Indications for Use of the Prodeon Urethral Sheath System is identical to that of the predicate device.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The Prodeon Urethral Sheath System has essentially the same technological characteristics as the predicate device. Both devices are comparable in their material composition, design, mechanical characteristics, and their use. The devices are both single use and are sterilized with EtO.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

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

General performance testing, including:

- Dimensional (OD, ID, Length)
- Scope compatibility (Irrigation Valve Compatibility, Leak)
- Sheath integrity
- Bond strength
- Shelf-life testing to support up to a 38-month shelf-life

Test results demonstrate that the Prodeon Urethral Sheath System meets all predetermined acceptance criteria.

The following Biocompatibility testing was performed:

- Cytotoxicity per ISO 10993-5:2009
- Sensitization per ISO 10993-10:2010
- Irritation per ISO 10993-10:2010

Based on the results of the testing, the Prodeon Urethral Sheath System is biocompatible.

Sterilization by ethylene oxide has been validated for the Prodeon Urethral Sheath System in accordance with ISO 11135:2014.

The nonclinical testing of the device demonstrates the Prodeon Urethral Sheath System meets its design requirements. The testing also demonstrates the substantial equivalence in characteristics to the predicate device.