November 1, 2024

Applied Medical Technology, Inc.
Jennifer Hazou
Regulatory Affairs Specialist
8006 Katherine Boulevard
Brecksville, OH 44141

Re: K240514
Trade/Device Name: AMT Low-Profile Suprapubic Catheter & Drainage Set
Regulation Number: 21 CFR§ 876.5090
Regulation Name: Suprapubic urological catheter and accessories
Regulatory Class: II
Product Code: KOB
Dated: October 4, 2024
Received: October 4, 2024

Dear Jennifer Hazou:

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,

Angel A. Soler-garcia -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

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)*
K240514

Device Name
AMT Low-Profile Suprapubic Catheter & Drainage Set

Indications for Use *(Describe)*
The AMT Low-Profile Suprapubic Catheter & Drainage Set is indicated for patients 7 years of age and older with lower urinary tract dysfunctions such as neurogenic bladder dysfunction, congenital malformation or urethral obstruction, or who are severely disabled or requiring constant care. The AMT Low-Profile Suprapubic Catheter & Drainage Set is indicated to be used for temporary suprapubic urinary diversion and drainage for less than or equal to four weeks. The AMT Low- Profile Suprapubic Catheter is intended to be placed directly into the bladder through a secured (initial placement) or formed (replacement) stoma.

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

AMT Low-Profile Suprapubic Catheter & Drainage Set

I. SUBMITTER:

Applied Medical Technology, Inc.
8006 Katherine Boulevard
Brecksville, OH 44141
Phone: 440-717-4000
Fax: 440-717-4200

Contact Person: Jennifer Hazou – Regulatory Affairs Specialist
Email: Jennifer.Hazou@appliedmedical.net
Date Prepared: November 1, 2024

II. DEVICE INFORMATION:

Trade/Device Name: AMT Low-Profile Suprapubic Catheter & Drainage Set
Regulation Name: Suprapubic Urological Catheter and Accessories
Regulation Number: 21 CFR 876.5090
Review Panel: Gastroenterology/Urology
Regulatory Class: II
Product Code: KOB

III. PREDICATE/REFERENCE INFORMATION:

Predicate Device: K181097 (Cook Cystostomy Catheter Set; Cook Incorporated)

Reference Device: K161413 (Low-Profile Balloon Feeding Device; Applied Medical Technology, Inc.)

**** The predicate/reference devices have <u>not</u> been subject to design-related recalls.**

IV. INDICATIONS FOR USE:

The AMT Low-Profile Suprapubic Catheter & Drainage Set is indicated for patients 7 years of age and older with lower urinary tract dysfunctions such as neurogenic bladder dysfunction, congenital malformation or urethral obstruction, or who are severely disabled or requiring constant care. The AMT Low-Profile Suprapubic Catheter & Drainage Set is indicated to be used for temporary suprapubic urinary diversion and drainage for less than or equal to four weeks. The AMT Low-Profile Suprapubic Catheter is intended to be placed directly into the bladder through a secured (initial placement) or formed (replacement) stoma.

V. DEVICE DESCRIPTION:

The Applied Medical Technology, Inc. (AMT) Low-Profile Suprapubic Catheter & Drainage Set (LPSPC) consists of two primary assemblies. The LPSPC is identical in materials and manufacturing processes to the Low-Profile Balloon Feeding Device cleared in K161413 for a different indication.

The Suprapubic Catheter is used to provide urinary diversion and drainage through the lower abdomen, placed and maintained in a percutaneously prepared cystostomy opening. The Drainage Set is intended to allow a connection between the suprapubic catheter device and a urinary collection bag system. The device is designed for bladder drainage by way of a secured (initial placement) or formed (replacement) cystostomy tract and may be used for irrigation. Patients may include: any user with urethral trauma, those who require long-term catheterization and urethral catheterization is intolerable, or those with a spinal cord injury and an inability to self-catheterize who may find the suprapubic method simpler to manage.

The LPSPC is a urinary drainage device made principally of silicone elastomer. The device consists of an internal retention balloon and a flexible external bolster with a balloon fill-valve, interlocking irrigation port, and safety plug. The catheter is inserted through the stoma and into the urinary bladder and is secured by the internal retention balloon. The device is offered in various sizes to accommodate different stoma diameters and lengths. On the shaft near the end is located a balloon which, when properly inflated, acts as an internal stabilizer preventing outward displacement through the stoma in the abdominal wall. The balloon is inflated through a separate inflation valve located in the external portion of the device.

The external profile of the device acts as a stabilizer to prevent inward migration and affords the user the ability to connect a provided Drainage Set.

The Drainage Set is identical in material and manufacturing process to certain configurations of the Irrigation Set included with the AMT Bowel Management Device previously cleared in K180026. The right-angle connector of the Drainage Set is compatible with the interlock on the LPSPC and is used to direct fluids drained from the bladder, through the catheter, and into a separate urinary collection bag.

The AMT Low-Profile Suprapubic Catheter & Drainage Set may optionally be marketed with a Foley Insertion Tray accessory. If included, the accessory would be a legally marketed Foley Insertion Tray, such as:

- AMSure Foley Insertion Tray (previously cleared Class II, Product Code FCM, K030664)
- Bardia Foley Insertion Tray (registered Class II, Product Code OHR, 510(k) exempt)
- Dynarex Foley insertion Tray without Catheter (registered Class II, Product Code OHR, 510(k) exempt)

The device is sold as sterile and can be initially placed in an outpatient-setting by a health care professional. The device may be replaced in an outpatient-setting or home setting by a health care professional or care giver.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE/REFERENCE DEVICES:

TABLE 5.1- TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE/REFERENCE DEVICES

	Subject Device:	**Predicate Device (K181097):**	**Reference Device (K161413):**
Device Class and Product Code:	Class II; KOB	Class II; KOB	Class II; KNT
	Substantial Equivalence:	Same	Different
Sterilization:	Sterile (Ethylene Oxide)	Sterile (Ethylene Oxide)	Sterile (Ethylene Oxide)
	Substantial Equivalence:	Same	Same
Prescription	Single use: Prescription Only	Single use: Prescription Only	Single use: Prescription Only
	Substantial Equivalence:	Same	Same
Indications for Use:	The AMT Low-Profile Suprapubic Catheter & Drainage Set is indicated for patients 7 years of age and older with lower urinary tract dysfunctions such as neurogenic bladder dysfunction, congenital malformation or urethral obstruction, or who are severely disabled or requiring constant care. The AMT Low-Profile Suprapubic Catheter & Drainage Set is indicated to be used for temporary suprapubic urinary diversion and drainage for less than or equal to four weeks. The AMT Low- Profile Suprapubic Catheter is intended to be placed directly into the bladder through a secured (initial placement) or formed (replacement) stoma.	The Cook® Cystostomy Catheter Set is used for temporary suprapubic urinary diversion and drainage for less than or equal to four weeks.	The Low-Profile Balloon Feeding Device is indicated for use in patients who require long term feeding, are unable to tolerate oral feeding, who are at low risk for aspiration, require gastric decompression and/or medication delivered directly into the stomach through a secured (initial placement) or formed (replacement) stoma. The Low-Profile Balloon Feeding Device is intended for all age groups.
	Substantial Equivalence:	Same	Different

Intended Use:	The AMT Low-Profile Suprapubic Catheter & Drainage Set provides the user a channel through which urinary bladder contents may be diverted directly from the bladder through the abdominal wall by way of a stoma.	The Cook Cystostomy Catheter Set provides the user a channel through which urinary bladder contents may be diverted directly from the bladder through the abdominal wall by way of a stoma.	The Low-Profile Balloon Feeding Device is indicated for use in patients who require long term feeding, are unable to tolerate oral feeding, who are at low risk for aspiration, require gastric decompression and/or medication delivered directly into the stomach through a secured (initial placement) or formed (replacement) stoma.
	Substantial Equivalence:	Same	Different

TABLE 5.1- TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE/REFERENCE DEVICES

	Subject Device:	**Predicate Device (K181097):**	**Reference Device (K161413):**
Principles of Operation	The device features a bi-lumen silicone tube overmolded on one end with a low-profile silicone bolster through which bladder contents may be drained, by way of a polycarbonate interlock. Opposite the bolster, the tubing is tipped on one end with a silicone tip, bonded directly to an inflatable silicone balloon that acts as an internal bolster to prevent outward migration of the device. The Drainage Set can interface with the polycarbonate interlock of the catheter in order to further direct the flow of drainage into an external urinary collection device.	The Cook Cystostomy Catheter Set is composed of a single-lumen silicone catheter through which bladder contents may be drained. The catheter is externally retained by a silicone catheter support. The external end of the catheter may be affixed with the provided stopcock, which can act to restrict flow and connect the device to an external urinary collection device.	The device features a bi-lumen silicone tube overmolded on one end with a low-profile silicone bolster through which nutrition and medication may be delivered, by way of a polycarbonate interlock. Opposite the bolster, the tubing is tipped on one end with a silicone tip, bonded directly to an inflatable silicone balloon that acts as an internal bolster to prevent outward migration of the device.
	Substantial Equivalence:	Similar	Similar
Design Similarities	1. Devices have direct access to a hollow organ (bladder or stomach) through the abdominal wall. 2. All devices permit flow in both directions (drainage/decompression and/or irrigation/feeding). 3. All devices feature soft silicone components where in patient contact. 4. All devices are offered in various French sizes for adult and pediatric use.		
Design Differences	1. The subject and reference devices feature a balloon which provides internal retention of the device when inflated while the predicate device does not contain an internal retention feature. 2. The subject and reference devices are low profile devices, featuring an anti-reflux device that requires the engagement of an extension set in order to permit flow from the hollow organ. The predicate device is a traditional length tube that does not require an additional extension set to permit flow. Flow through the predicate device can only be stopped with the included stopcock. 3. The low-profile device is configured in fixed lengths to be selected for certain abdominal wall thicknesses, while the predicate device is adjustable across a range of patient anatomy. 4. The predicate device includes a trocar stylet to aid initial placement of the catheter. Subject and reference devices do not include an initial placement trocar. 5. The predicate device is meant to be secured with sutures or tape to the abdominal wall. The subject device does not require suture securement.		

VII. PERFORMANCE DATA:

A. Biocompatibility Testing: The AMT Low-Profile Suprapubic Catheter & Drainage Set was tested for biocompatibility based on the applicable sections of the following standards:

- ISO 10993-1 Fifth edition 2018-08 - Biological evaluation of medical devices
  --Part 1: Evaluation and testing within a risk management process
- ISO 10993-3 Third edition 2014-10-1 - Biological evaluation of medical devices
  --Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
- ISO 10993-5 Third edition 2009-06-01 - Biological evaluation of medical devices
  --Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6 Third edition 2016-12-01 - Biological evaluation of medical devices
  --Part 6: Tests for local effects after implantation
- ISO 10993-7 Second edition 2008-10-15 - Biological evaluation of medical devices
  --Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10 Fourth edition 2021-11 - Biological evaluation of medical devices
  --Part 10: Tests for skin sensitization
- ISO 10993-11 Third edition 2017-09 - Biological evaluation of medical devices
  --Part 11: Tests for systemic toxicity
- ISO 10993-12 Fourth edition 2012-07-01 - Biological evaluation of medical devices
  --Part 12: Sample preparation and reference materials
- ISO 10993-17 First edition 2002-12-01 - Biological evaluation of medical devices
  --Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18 Second edition 2020-01 Amendment 1 2022-05 - Biological evaluation of medical devices
  --Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 10993-23 First edition 2021-01 - Biological evaluation of medical devices
  --Part 23: Tests for irritation

It was determined that the AMT Low-Profile Suprapubic Catheter & Drainage Set met the acceptance criteria for permanent contact (greater than 30 days) with mucosal membrane and breached/compromised surfaces.

B. Software: There are no software components related in any way to this device. Therefore, Software Validation is not applicable to this device.

C. Electromagnetic Compatibility & Electrical Safety: There are no electronic components related in any way to this device.

D. Performance Testing:

1. Sterilization

Testing has been completed to evaluate the sterilization process for the subject device, and is outlined below:

- Testing per ISO 11135, Second edition 2014-07-15
    - Sterilization of health-care products – Ethylene oxide – Requirements for the development validation and routine control of a sterilization process for medical devices

- Testing per ISO 10993-7, Second edition 2008-10-15
    - Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

The subject device is ethylene oxide sterilized, and has been validated to confirm a Sterility Assurance Level (SAL) of 10^{-6}. The sterilization processing complies with the standards.

2. Shelf Life

The sterilized packaging for the subject device was tested in accordance with the following:

- Testing in accordance with ASTM F1980-21:
    - Standard guide for accelerated aging of sterile barrier systems for medical devices

- Testing per ISO 11607-1 & 2, Second edition 2019-02:
    - Packaging for terminally sterilized medical devices

- Testing per ISTA 3A 2018:
    - Packaged products for parcel delivery system shipment 70kg (150 lb) or less

Testing of the sterile barrier system has indicated that the packaging for the subject device complies with the standards.

3. Bench Testing

Bench tests have been carried out to demonstrate conformance to applicable recognized standards and to assure reliable design and performance under the specified testing parameters according to predetermined criteria. The tests carried out include:

- Testing per AMT Design Specifications:
    - Balloon Assembly Bond Peel/Tear Strength
    - Balloon Burst
    - Fill Valve Blow Out
    - Fill Valve Pullout
    - Flow Rate
    - Leak Test
    - Tubing Tensile Strength
    - Minimum Overmold Bond Strength
    - Stoma Pullout
    - Tubing Cyclic and Tensile Test
    - Main Strap Tensile Strength
    - Side Strap Tensile Strength

- Testing per ASTM F2052-21:
    - Measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment

- Testing per ASTM F2213-17:
  - Measurement of magnetically induced torque on medical devices in the magnetic resonance environment

- Testing per ASTM F2119-07 (Reapproved 2013):
  - Evaluation of MR image artifacts from passive implants

- Testing per ASTM F2182-19e2:
  - Measurement of radio frequency induced heating on or near passive implants during magnetic resonance

- Testing per ISO 20695 First edition 2020-03
  - Enteral feeding systems – Design and testing

- Testing per ASTM F2528-06 (Reapproved 2023)
  - Standard Test Methods for Enteral Feeding Devices with a Retention Balloon

- Testing per ISO 80369-1 Second edition 2018-11
  - Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements

The AMT Low-Profile Suprapubic Catheter & Drainage Set met or exceeded all the acceptance criteria and does not raise new questions of safety or effectiveness when compared to the predicate/reference devices.

E. Animal Study: Animal testing was NOT performed.

F. Clinical Study: Clinical evidence gathered from independent organizations in the form of a systematic literature review was included in this submission to provide support for the use of a Low-Profile Balloon Feeding Device as a suprapubic catheter and allowing initial placement of the device. Articles from 1996 to 2024 were included. No date limiting parameters were applied to the database searches.

Sources Used to Identify Data:
Published Literature Databases:

- PubMed
- EBSCO
- Google Scholar

Selection Criteria
The following criteria were used to assess the suitability of material (articles, reports, etc.) for inclusion in the analysis stage of this report:

- Article addresses performance, risks, and/or safety of devices used for the proposed indication of suprapubic catheterization; or
- Article addresses technique for initial placement of a suprapubic catheter into the bladder, particularly the placement of a low-profile gastrostomy device.

A total of 22 articles were considered relevant to the proposed indications for use (IFU) and were reviewed and provided for FDA assessment. The reporting of this systematic review was guided by

the standards of the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) Statement, as well as the Cochrane Handbook for Systematic Reviews of Interventions. Assessment of the included literature was completed using the critical appraisal tools published by the Joanna Brigges Institute. In addition, FDA's guidance for Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices was referenced to help identify published literature directly addressing the new IFU statement.

In these 22 published articles, clinical experience was reported on 34 adults and 188 pediatric patients undergoing vesicostomies with the subject device or similar devices used in initial placement or replacement procedures. Reports of use extended from days to months and as long as 3 years in duration. Information was also sourced from a guideline created through an independent collaboration by the Pediatric Urologists of Canada and the Canadian Urological Association regarding an evidence-based guideline for the multidisciplinary management of pediatric patients with neurogenic lower urinary tract dysfunction (NLUTD). Also source information from an operative textbook detailing a technique for button vesicostomy was reviewed. Finally, information cited by the International Continence Society (ICS) published to provide a clinically based guide on male lower urinary tract (LUT) terminology to aid clinical practice and research was considered.

Common risks associated with the device and its placement include hematuria, wound infection, urinary tract infection (UTI), leakage, poor fit, discomfort, and bladder spasms. The data shows that for the intended user population this device will allow for continent retention of urine with complete bladder emptying upon intermittent catheterization through the device and does not entail any anticipated risks apart from those seen with this device type (suprapubic cystostomy). The overall benefit of the device includes allowing a less conspicuous drainage site, convenient intermittent catheterization and much less interference with activities of daily living. Based on the clinical information, the device was determined to function clinically as intended and that the benefits outweigh the risks in the target user population.

G. CONCLUSION:

The AMT Low-Profile Suprapubic Catheter & Drainage Set can be found substantially equivalent to the predicate device cleared under K181097 in intended use, performance, and principles of operation. The subject device can be found substantially equivalent to the reference device cleared under K161413 in material composition and design. Bench testing of the AMT Low-Profile Suprapubic Catheter & Drainage Set demonstrates that the subject device meets or exceeds all predetermined specifications for performance principles. The design differences between the subject device and the legally marketed predicate chiefly reflect the differences between a traditional-length device and a low-profile one, and do not raise different questions of safety and/or efficacy. The information submitted in this application demonstrates that the subject device is substantially equivalent to existing legally marketed devices for the intended use, but in a low-profile form with a removable extension set.