August 5, 2026

Class Medical , Ltd.
% David Worrell
Regulatory Consultant
Rqm+
5000 Centregreen Way
Suite 100
Cary, North Carolina 27513

Re: K260919
Trade/Device Name: Transurethral Catheter Safety Valve (TUCSV) (80050)
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: KNY
Dated: July 3, 2026
Received: July 6, 2026

Dear David Worrell:

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 13484 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 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 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,

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260919

Please provide the device trade name(s).

Transurethral Catheter Safety Valve (TUCSV) (80050)

Please provide your Indications for Use below.

The TUC Safety Valve is indicated for single use during inflation of a Foley catheter retaining balloon in adult patients. The TUCSV alerts the user of premature inflation of the balloon within the urethra and alleviates the pressure, to aid in the prevention of incorrect balloon placement.

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

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

510(K) SUMMARY

A. Applicant Name, Address, Telephone

Applicant name	Class Medical Ltd.
Applicant address	Unit 1D Annacotty Business Park Annacotty Co. Limerick, Ireland
Applicant phone	+353 85 2823340

B. Applicant Contact

Mr. Danny Forde
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C. Primary Correspondent/Consultant

David Worrell
Regulatory Consultant
RQM+
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D. Date Prepared

August 5, 2026

E. Device Name

Device trade name:	Transurethral Catheter Safety Valve (TUCSV) (80050)
Device common name:	Catheter accessory
Classification name:	Urological catheters and accessories
Device class:	Class II
Classification regulation	21 CFR 876.5130
Product Codes:	KNY

F. Predicate Device

Signal Catheter K182635. The predicate device has not been subject to a design-related recall.

G. Device Description

The TUCSV Device is a sterile, single-use accessory that is used in conjunction with a Foley balloon-type catheter during urological procedures. The TUCSV is placed between the inflation syringe and the retention balloon catheter using standard Luer connections. The device contains a flow restrictor to minimize rapid inflation of the retention balloon. It incorporates a pressure relief valve to expel inflation fluid which indicates misplacement of the retention balloon within the urethra. This aids in the prevention of incorrect balloon placement (e.g., if the balloon is inadvertently inflated before entering the bladder).

H. Indications for Use

The TUC Safety Valve is indicated for single use during inflation of a Foley catheter retaining balloon in adult patients. The TUCSV alerts the user of premature inflation of the balloon within the urethra and alleviates the pressure, to aid in the prevention of incorrect balloon placement.

I. Comparison of Technological Characteristics

The subject device Transurethral Catheter Safety Valve is substantially equivalent to the predicate device with respect to same intended use, and similar indications for use, technology, materials of construction, and performance. Table 1 summarizes the comparison between the subject device and the predicate device.

Table 1. Comparison of Subject Device and Predicate Device

Features	Class Medical Ltd. TUCSV Device	Safe Medical Design Signal Catheter K182635
	Subject device	**Predicate device**
Device Classification	21 CFR 876.5130	
Common Name	Urological Catheter and Accessories	
Indications for Use	The TUC Safety Valve is indicated for single use during inflation of a Foley catheter retaining balloon in adult patients. The TUCSV alerts the user of premature inflation of the balloon within the urethra and alleviates the pressure, to aid in prevention of incorrect balloon placement.	The Signal Catheter is indicated for urological bladder drainage, with a maximum patient indwelling time of 29 days.
Technology - Mechanism of Action for Pressure Relief	The TUCSV is positioned between the inflation syringe and the balloon catheter using standard Luer connections. It uses a pressure relief valve to indicate pressurization and misplacement of the retention balloon within the urethra. Inflation fluid is expelled from the valve to alleviate the pressure and inflation of the retention balloon.	The signal balloon is an integral component and positioned in the catheter proximal hub. It is designed to inflate during excessive pressure in the retention balloon when it is constricted or misplaced within the urethra. The signal balloon inflates to alleviate the fluid inflation and resulting pressure in the retention balloon.
Device Activation	Occurs when the retention balloon is constricted within the urethra when it cannot be safely inflated at the nominal inflation parameters of the catheter.	
Inflation Fluid Flow Restriction	Flow rate is regulated by integrated restrictor screw to minimize rapid inflation of the retention balloon.	Flow rate is user controlled via force of syringe depression for retention balloon inflation.

Features	Class Medical Ltd. TUCSV Device	Safe Medical Design Signal Catheter K182635
	Subject device	**Predicate device**
Patient Contact	No. TUCSV is placed between the syringe and catheter and is external to the patient.	Yes. Balloon catheter inserted into the urethra and bladder. The auxiliary signal balloon is external to the patient.
Material	Medical Grade Plastic and Silicone	Silicone
Sterile Single Use	Yes	Yes

The subject device and predicate device have the same intended use. The subject device and predicate device are sterile, single-use devices intended to prevent injury from accidental inflation of the retention balloon in the urethra.

The subject device and predicate device use different technological characteristics to perform the same general purpose to alert the user to inadvertent retention balloon inflation when the balloon is misplaced within the urethra. The TUCSV device has a valve external to the balloon catheter that releases excess inflation fluid when the retention balloon is inflated in the urethra. The predicate device contains an external balloon within the catheter hub that inflates with fluid when the retention balloon is inflated in the urethra. When the subject device and predicate device are used as intended, they achieve the same general purpose and these differences in technological characteristics do not raise different questions of safety and effectiveness.

J. Summary of Non-Clinical Testing

Bench testing of the subject device met all predetermined acceptance criteria, and included:

- Dimensional verification testing
- Compatibility with commercially available fluid-filled syringes and Foley-type catheters
- Pressure-release testing
- Retention balloon flow-rate testing
- Pull-tab force testing
- Valve repeatability testing
- Luer connection testing per FDA-recognized standard ISO 80369-7 Second edition 2021-05 – *Small bore connectors for liquids and gases in healthcare applications*

Shelf-life testing was conducted using the following FDA-recognized standards:

- Accelerated Aging: ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- Environmental Conditioning: ASTM D4332-22 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- Simulated Distribution ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
- Sterile Barrier Integrity: Dye Penetration ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

- Seal Strength Testing: ASTM F88-23 Standard Test Method for Seal Strength of Flexible Barrier Materials

The TUCSV device is provided STERILE and for single use only. The sterilization method is radiation (R). A sterilization validation was performed according to the following FDA-recognized standards:

- ISO 11137-1:2006/(R)2015 Sterilization of healthcare products – Radiation Part 1
- ISO 11137-2 Third edition 2013-06 [Including AMD1:2022] – Sterilization of healthcare products – Radiation Part 2

Sterile barrier systems were evaluated for performance and stability in accordance with ISO 11607-1:2019 Requirements for materials, sterile barrier systems, and packaging systems.

Usability Engineering FDA-recognized standards IEC 62366-1:2015/A1:2020 Medical Devices – Part 1: Application of usability engineering to medical devices processes and FDA Guidance *Applying Human Factors and Usability Engineering to Medical Devices, dated February 3, 2016*, were used to plan and conduct a usability study for the TUCSV device. Specific use scenarios and tasks were identified, and an analysis of hazards and risks was conducted to determine safety risks associated with use of the subject device. All critical tasks were evaluated by the human factors study. The usability study was completed successfully. No changes to the device design or device labeling were considered necessary based on results of the usability factors study.

A GLP animal study compared urethral tissue response from inflation of the anchoring balloon of a urinary catheter, to demonstrate that the activation pressures of the device do not cause urethral damage. No macroscopic or histological abnormalities were observed between the two groups. Histomorphometry results showed urethral wall thickness was comparable for the two groups. Results from the animal study confirmed no significant urethral tissue response at anchoring balloon inflations in the urethra at clinically relevant high pressure compared to low pressure in the animal model.

K. Summary of Clinical Testing

A post-market, 3-month prospective, multi-center, open label, single-arm registry study was conducted in Ireland and the United Kingdom. A concurrent control population was included in the study which included patients from clinical areas at three study sites where the TUCSV device was not made available. The objective of the study was to determine the safety and effectiveness of the TUCSV when used in conjunction with a urethral catheter. The patient population included adult male or female (Age ≥18) patients with no known pre-existing urethral anomaly requiring the placement of a urinary catheter who provided consent to participate in the study.

The intention to treat (ITT) population included 1,014 patients, including 839 males and 175 females. The per protocol (PP) population included 911 patients, including 739 males and 172 females. A post-hoc analysis was conducted to evaluate the following endpoints:

1. **Primary Safety and Efficacy Endpoint**: Rate of catheter balloon injury (CBI). Analysis was performed on the intent-to-treat population: 0.0%

   Suspected catheter balloon injuries were confirmed by a Urologist in an examination immediately following the catheterization procedure.

CBI was defined as failure to complete urethral catheterization after balloon inflation with associated failure to drain the bladder normally and severe pain in awake patients, usually accompanied by urethral bleeding/hematuria.

2. **Secondary Endpoint**: Device Accuracy Performance. Device Accuracy was analyzed as sensitivity and specificity of the device in indicating to the user that the balloon is placed correctly or incorrectly. Analysis was performed on the per protocol population only. Accuracy was calculated as follows:

    - Sensitivity of the device to incorrect catheter placement – Percent rate of TUCSV vents correctly when the balloon is inflated in the urethra: 100%
    - Specificity of the device to correct placement – Percent rate of TUCSV not venting correctly when the balloon is inflated in the bladder: 99.7%
    - Percent of inappropriate venting (false positive): 0.3%
    - Percent of failed venting when balloon was inflated in the urethra (false negative): 0.0%
    - Positive predictive value (PPV) - the proportion of venting events in which the balloon was in fact malpositioned. Calculated as true positives divided by all venting events (true positives plus false positives): 83.3%
    - Negative predictive value (NPV) - the proportion of non-venting procedures in which the balloon was in fact correctly placed. Calculated as true negatives divided by all non-venting procedures (true negatives plus false negatives): 100%
    - Accuracy - the proportion of all procedures in which the device correctly indicated balloon position, whether by venting or not venting. Calculated as true positives plus true negatives, divided by the total number of procedures: 99.7%

The study procedure achieved a 100% success rate for the TUCSV arm where catheterization was successful. The observed vent rate was 1.97% in the TUCSV arm. No CBIs were reported in the ITT population (TUCSV arm). No CBIs were reported in the PP population (TUCSV arm). In the concurrent control population, against an estimated 4,648 catheterizations over the 3-month monitoring period, the CBI was 1.24% in males, 0.22% in females and 0.73% overall.

No urethral injury occurred with the TUCSV. One adverse event was reported which met the definition of a serious adverse event but was classified unrelated to the device or procedure. Three pain events were reported at venting; all were deemed as normal procedural discomfort anticipated with successful catheterization.

24 protocol deviations were identified, all in the TUCSV arm, where the case report form incorrectly documented 'No' or 'NA' to the question "Was the TUCSV used as per the instructional video?". All 24 procedures were successful.

L. Conclusion

Non-clinical performance testing results demonstrate the subject device meets established specifications, met pre-determined acceptance criteria and conforms with FDA-recognized standards for medical devices. The subject device performs as well as the predicate device for its intended use and supports a determination of substantial equivalence.

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