April 4, 2025

Turbett Surgical
Melissa Conley
Director of Quality and Regulatory Affairs
245 Summit Point Drive
Suite 2A
Henrietta, New York 14467

Re: K250011
Trade/Device Name: Turbett Surgical Instrument Pod (TS1500); Turbett Surgical Instrument Pod (TS1200); Turbett Surgical Instrument Pod (TS1000)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: January 2, 2025
Received: January 2, 2025

Dear Melissa Conley:

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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and
Infection Control 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)*
K250011

Device Name
Turbett Surgical Instrument Pod

Indications for Use *(Describe)*

The Turbett Surgical Instrument Pod is indicated for enclosing other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed materials and maintain sterility for up to 30 days until used. The unit is intended to be used in pre-vacuum steam sterilizers. The unit must be used with Turbett Surgical Filters.

The unit is intended to be used in a pre-vacuum steam sterilizers with a pre-vacuum cycle of 270°F (132°C) and exposure time of 4 minutes.

•The TS1500 Container may be loaded to a maximum weight of 375 lbs., not to exceed 25 lbs. in any tray. Minimum drying time for loads up to 140lbs. is 10minutes, for loads up to 375 lbs. is 30 minutes.
•The TS1200 Container may be loaded to a maximum weight of 300 lbs., not to exceed 25 lbs. in any tray. Minimum drying time is 10 minutes for loads up to120 lbs. and 30 minutes for loads up to 300 lbs.
•The TS1000 Container may be loaded to a maximum weight of 100 lbs., not to exceed 25 lbs. in any tray. Minimum drying time is 10 minutes.
•The system was validated with 0.7 mm x 500 mm and 1.0 mm x 850 mm rigid and flexible lumens.

Use only uncovered, perforated, or wire mesh general delivery trays within the Turbett Surgical Instrument Pod.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# K250011 - 510(k) Summary

## Submitter

| | |
|---|---|
| **510(k) Owner:** | Turbett Surgical<br>245 Summit Point Drive<br>Suite 2A<br>Henreitta, NY 14467 |
| **Official Correspondent:** | Melissa Conley<br>Director of Quality and<br>Regulatory Affairs<br>Turbett Surgical, Inc.<br>(412) 901-6650 |
| **Date of Preparation:** | 03/26/2025 |

## Device

| | |
|---|---|
| **Proprietary/Trade Name:** | Turbett Surgical Instrument Pod |
| **Common/ Usual Name:** | Sterilization Wrap/ Container |
| **Device Classification:** | II |
| **Classification Name/ Product Code:** | 21 CFR 880.6850 / FRG |
| **Primary Predicate Device:** | Turbett Surgical Instrument Pod, K202593 |
| **Submission Reason:** | Indications expansion |

## Device Description

The Turbett Surgical Instrument Pod is a multi-tray rigid sterilization container with a fenestrated door holding a single use filter. The container is designed to be used in a steam autoclave and hold multiple open trays containing surgical instruments. Unwrapped, uncovered, perforated sterilization trays are stacked into the container, separated by anodized aluminum dividers, which allow steam to evenly penetrate and allow condensation to drain.

The container is manufactured from 304 stainless steel sheet metal and bar stock. The container is sealed on all sides except one which is the door / filter panel.

The single fenestrated door consists of two perforated anodized aluminum panels which cover the exposed container side wall. A custom-made disposable filter consisting of 2 layers of filter paper separated by a layer of compressible single - use gasket material is placed between the two perforated metal panels of the door. Spring loaded latches compress the anodized aluminum door frame with filter assembly to the container for a secure seal.

The Turbett Surgical Instrument Pod is loaded into the auto clave with a dedicated transfer mechanism and cart.

## Indications for Use

The Turbett Surgical Instrument Pod is indicated for enclosing other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed materials and maintain sterility for up to 30 days until used. The unit is intended to be used in pre-vacuum steam sterilizers. The unit must be used with Turbett Surgical Filters.

The unit is intended to be used in a pre-vacuum steam sterilizers with a pre-vacuum cycle of 270°F (132°C) and exposure time of 4 minutes.

• The TS1500 Container may be loaded to a maximum weight of 375 lbs., not to exceed 25 lbs. in any tray. Minimum drying time for loads up to 140lbs. is 10 minutes, for loads up to 375 lbs. is 30 minutes.
• The TS1200 Container may be loaded to a maximum weight of 300 lbs., not to exceed 25 lbs. in any tray. Minimum drying time is 10 minutes for loads up to 120 lbs. and 30 minutes for loads up to 300 lbs.
• The TS1000 Container may be loaded to a maximum weight of 100 lbs., not to exceed 25 lbs. in any tray. Minimum drying time is 10 minutes.
• The system was validated with 0.7 mm x 500 mm and 1.0 mm x 850 mm rigid and flexible lumens.

Use only uncovered, perforated, or wire mesh general delivery trays within the Turbett Surgical Instrument Pod.

## Comparison of Technological Characteristics with the Predicate Device

| Characteristic | Subject Device | Predicate Device, K202593 | Comparison |
|---|---|---|---|
| Regulation and Product Classification Code | 21 CFR 880.6850<br>FRG | 21 CFR 880.6850<br>FRG | Same. |
| Indications for Use | The Turbett Surgical Instrument Pod is indicated for enclosing other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed materials and maintain sterility for up to 30 days until used. The unit is intended to be used in pre-vacuum steam sterilizers. The unit must be used with Turbett Surgical Filters.<br><br>The unit is intended to be used in a pre-vacuum steam sterilizers with a pre-vacuum cycle of 270°F (132°C) and exposure time of 4 minutes.<br><br>• The TS1500 Container may be loaded to a maximum weight of 375 lbs., not to exceed 25 lbs. in any tray. Minimum drying time for loads up to 140lbs. is 10 minutes, for loads up to 375 lbs. is 30 minutes.<br>• The TS1200 Container may be loaded to a maximum weight of 300 lbs., not to exceed 25 lbs. in any tray. Minimum drying time is 10 minutes for loads up to 120 lbs. and | The Turbett Surgical Container is indicated for enclosing other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed materials and maintain sterility for up to 30 days until used. The unit is intended to be used in pre-vacuum steam sterilizers. The unit must be used with Turbett Surgical Filters.<br><br>The unit is intended to be used in pre-vacuum steam sterilizers with a pre-vacuum cycle of 270°F (132°C) and exposure time of 4 minutes.<br><br>• The TS1500 Container may be loaded to a maximum weight of 375 lbs., not to exceed 25 lbs. in any tray. Minimum drying time for loads up to 140lbs. is 10 minutes, for loads up to 375 lbs. is 30 minutes.<br>• The TS1200 Container may be loaded to a maximum weight of 120lbs., not to exceed 25 lbs. in any tray. Minimum drying time is 10 minutes. | The intended use of the device, allowing the sterilization of enclosed materials and maintaining sterility for up to 30 days until used, remains the exact same between the predicate device and the subject device.<br><br>The indications for lumen sizes that are to be sterilized and the maximum weight capacity for the TS1200 model are different between the predicate and the subject device. The subject device proposes the sterilization of thinner and longer, both rigid and flexible lumens and a the TS1200 |

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| | 30 minutes for loads up to 300 lbs.<br>• The TS1000 Container may be loaded to a maximum weight of 100 lbs., not to exceed 25 lbs. in any tray. Minimum drying time is 10 minutes.<br>• The system was validated with 0.7 mm x 500 mm and 1.0 mm x 850 mm rigid and flexible lumens.<br><br>Use only uncovered, perforated, or wire mesh general delivers trays within the Turbett Surgical Instrument Pod. | • The TS1000 Container may be loaded to a maximum weight of 100 lbs., not to exceed 25 lbs. in any tray. Minimum drying time is 10 minutes.<br>• The system was validated with 1mm x 500mm lumens.<br><br>Use only uncovered, perforated or wire mesh general delivery trays within the Turbett Instrument Pod. | model has been validated for up to 300 lbs. in the subject device, vs. 120 lbs. labeled for the predicate device. |
| Principal Material of Construction | Stainless Steel and Aluminum | Stainless Steel and Aluminum | Same. |
| Sterilization Parameters | 270°F (132°C) for 4 minutes | 270°F (132°C) for 4 minutes | Same. |
| Recommended Sterilization Trays | All manufacturers' trays – uncovered, perforated, or wire mesh general delivery trays. | All manufacturers' trays – uncovered, perforated, or wire mesh general delivery trays. | Same. |
| Recommended Sterilizers | All makes and models with dimensions compatible with the Turbett Surgical Instrument Pod and that are capable of achieving the required sterilization parameters of 270°F (132°C) for 4 minutes. | All makes and models with dimensions compatible with the Turbett Surgical Instrument Pod and that are capable of achieving the required sterilization parameters of 270°F (132°C) for 4 minutes. | Same. |
| Deployment into Sterilizer | Transfer Mechanism and Cart | Transfer Mechanism and Cart | Same. |
| Load | TS1500 up to 375lbs.<br><br>TS1200 up to 300 lbs.<br><br>TS1000 up to 100 lbs. | TS1500 up to 375 lbs.<br><br>TS1200 up to 120 lbs.<br><br>TS1000 up to 100 lbs. | Similar, The TS1200 model has been validated for up to 300 lbs. vs the predicate of 120 lbs. |
| Storage | Up to 30 days | Up to 30 days | Same. |
| Transportation | The TS1500, TS1200 and TS1000 may be transported. | The TS1500 may be transported. | The TS1500 model represents the |

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| | | | worst case model to be transported as it is the largest by size and holds the highest maximum load weight. |

## Performance Testing Data

### Non-Clinical Tests

The following non-clinical tests were completed and submitted/ referenced as part of this submission:

| Test Name | Method and/ or Standard | Acceptance Criteria | Results (Pass / Fail) |
|---|---|---|---|
| **Sterilization Efficacy** | ANSI/AAMI ST77:2013, Containment Devices for Reusable Medical Device Sterilization | Log reduction of $10^{-6}$ sterility assurance level | **Pass** |
| **Thermal Profile** | ANSI/AAMI ST77:2013, Containment Devices for Reusable Medical Device Sterilization | Demonstrate various locations within the container can reach and maintain exposure temperature | **Pass** |
| **Dry Time** | ANSI/AAMI ST79:2007, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities | Pre/Post weight difference less than 0.2% and no visible moisture after specified drying time | **Pass** |
| **30 Day Event Related Shelf Life** | ANSI/AAMI ST77:2013, Containment Devices for Reusable Medical | Contents remain sterile post 30-Day Shelf-life. | **Pass** |

| | | | |
|---|---|---|---|
| | Device Sterilization | | |
| **Cleaning Validation** | TIR 30:2011, A compendium of Processes, Materials, Test Methods and Acceptance Criteria for Cleaning Reusable Medical Devices. | Residual Protein and Total Carbon within test limits (Protein level of less than 6.4 µg/cm$^2$ and Total Carbon level of less than 2.2 µg/cm$^2$ ) | **Pass** |
| **Microbial Aerosol Challenge** | ANSI/AAMI ST77:2013, Containment Devices for Reusable Medical Device Sterilization | Demonstrate maintenance of sterility by no growth of internal test coupons following exposure to microbial aerosol | **Pass** |
| **Usability** | ANSI/AAMI HE75:2013, Human Factors Engineering - Design of Medical Devices. | Demonstrate that the device can be used by representative users under simulated use conditions without producing patterns of failures that could result in negative clinical impact to patients or injury to users.<br><br>Verify use of the IFU is effective.<br><br>Determine whether the use related safety issues associated with using the device have been adequately mitigated. | **Pass** |

**Clinical Tests**

Clinical tests were not required to demonstrate safety and effectiveness of the Turbett Surgical Instrument Pod. Safety and efficacy have been established through non-clinical tests.

**Conclusion**

The conclusions drawn from the nonclinical tests demonstrate that the subject device in 510(k) submission K250011, the Turbett Surgical Instrument Pod, is as

safe, as effective, and performs as well as or better than the legally marketed predicate device cleared in K202593.