



May 19, 2021

Turbett Surgical Inc.  
% David Furr  
Consultant  
FDC Services  
8708 Capehart Cove  
Austin, Texas 78733

Re: K202593

Trade/Device Name: Turbett Instrument Pod  
Regulation Number: 21 CFR 880.6850  
Regulation Name: Sterilization Wrap  
Regulatory Class: Class II  
Product Code: FRG  
Dated: April 13, 2021  
Received: April 22, 2021

Dear David Furr:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray, III, PhD  
Acting Assistant Director  
DHT4B: Division of Infection Control  
and Plastic Surgery Devices  
OHT4: Office of Surgical  
and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K202593

Device Name  
Turbett Instrument Pod

### Indications for Use (Describe)

The Turbett 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 the Turbett Surgical filters.

The unit is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270F (132C) 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 140 lbs. is 10 minutes, for loads up to 375 lbs. 30 minutes.
- The TS1200 Container may be loaded to a maximum weight of 120 lbs., not to exceed 25 lbs. in any tray. Minimum drying time is 10 minutes.
- 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 1mm x 500mm lumens.

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

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# 510(k) Summary K202593

**Date: May 16, 2021**

1. Submitted By: Turbett Surgical, Inc.  
125 Tech Park Drive  
Rochester, NY 14625  
585-755-0133
2. Contact: David C. Furr  
FDC Services, LLC  
8708 Capehart Cove  
Austin, Texas 78733  
512-906-9654
3. Product: Turbett Instrument Pod – TS1500, TS1200, TS1000  
Product code: FRG - Class II (21 CFR 880.6850)
4. Common/Classification  
Name: Sterilization wrap/container;  
Predicate device - Turbett Surgical Container K200240

## Description:

The Turbett Instrument Pod is a 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. Trays within the container are separated by dividers to ensure separation and maximum steam exposure. The container is available in three sizes (TS1500 34"x24"x22"; TS1200 34" x17" x22"; TS1000 23" x17" x 22"). The original container (TS1500) has been validated to sterilize 375 lbs. of instruments along with the dividers. The validation was conducted with 15 instrument trays at 25 lbs. each to represent the most challenging case. Additional containers include the TS1200 and TS1000 sizes which can hold 120 lbs. and 100 lbs. of instruments. Sterilized instruments can be transported and stored for up to 30 days within the closed container.

The Turbett Instrument Pod is loaded into the autoclave with a dedicated transfer carriage. The container is constructed of 304 stainless steel with an anodized aluminum filter housing/door.

The use of a single-use disposable filter cartridge installed in the fenestrated door eliminates the need for a sealed gasket found on other rigid containers. The omission of a reusable gasket eliminates contamination risks due to failed reusable gaskets.

### Intended Use:

The Turbett 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 the Turbett Surgical filters.

The unit is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270F (132C) 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 140 lbs. is 10 minutes, for loads up to 375 lbs. 30 minutes.
- The TS1200 Container may be loaded to a maximum weight of 120 lbs., not to exceed 25 lbs. in any tray. Minimum drying time is 10 minutes.
- 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 1mm x 500mm lumens. Do not use with instruments containing lumens with an inner diameter of smaller than 1mm and an overall length longer than 500mm.

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

### Technological Characteristics Table:

Shown below is the technological characteristics comparison table for the subject device with the predicate device.

Element of Comparison	510(k) Device: Turbett Instrument Pod K202593	Predicate Device: Turbett Instrument Pod K200240	Explanation of Differences
Regulation and Product Classification Code	21 CFR 880.6850 FRG	21 CFR 880.6850 FRG	None
Indications for Use	<p>The Turbett 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 the Turbett Surgical filters.</p> <p>The unit is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270F (132C) and exposure time of 4 minutes.</p> <ul style="list-style-type: none"> <li>• 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 140 lbs. is 10 minutes, for loads up to 375 lbs. 30 minutes.</li> <li>• The TS1200 Container may be loaded to a maximum weight of 120 lbs., not to exceed 25 lbs. in any tray. Minimum drying time is 10 minutes.</li> <li>• 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.</li> <li>• The system was validated with 1mm x 500mm lumens. Do not use with instruments containing lumens with an inner diameter of smaller than 0.5mm and an overall length longer than 500mm.</li> </ul> <p>Use only uncovered, perforated or wire mesh general delivery trays within the Turbett Instrument Pod.</p>	<p>The Turbett 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 the Turbett Surgical filters.</p> <p>The unit is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270F (132C) and exposure time of 4 minutes.</p> <ul style="list-style-type: none"> <li>• 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 140 lbs. is 10 minutes, for loads up to 375 lbs. 30 minutes.</li> <li>• The TS1200 Container may be loaded to a maximum weight of 120 lbs., not to exceed 25 lbs. in any tray. Minimum drying time is 10 minutes.</li> <li>• 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.</li> <li>• The system was validated with 1mm x 500mm lumens. Do not use with instruments containing lumens with an inner diameter of smaller than 1mm and an overall length longer than 500mm.</li> </ul> <p>Use only uncovered, perforated or wire mesh general delivery trays within the Turbett Instrument Pod.</p>	Indications are identical
Principal Material of Construction	Stainless Steel and aluminum	Stainless Steel and aluminum	Same
Overall Size	Approximate size TS1500 34"x24"x22" TS1200 34" x17" x22" TS1000 23" x17" x 22"	Approximate size TS1500 34"x24"x22" TS1200 34" x17" x22" TS1000 23" x17" x 22"	All pods are identical

Presentation of Device	Very Large Container with transfer cart, 3 sizes.	Very Large Container with transfer cart, 3 sizes.	All pods are identical
Sterilization Cycle	Prevacuum Steam 4 minute cycle 132°C	Prevacuum Steam 4 minute cycle 132°C	None
Load	TS1500 up to 375 lbs. TS1200 up to 120 lbs. TS1000 up to 100 lbs.	TS1500 up to 375 lbs. TS1200 up to 120 lbs. TS1000 up to 100 lbs.	All pods are identical
Storage	Up to 30 days	Up to 30 days	None
Transportation	TS1500 may be transported	None	Transport added

Summary of Non-Clinical Testing:

Provided below is the non-clinical testing performed with the subject device to demonstrate that the device met the acceptance criteria with the standard listed below.

Type of Testing	Purpose	Acceptance Criteria	Result
Pre-vacuum sterilization efficacy  AAMI ST77 Containment Devices for Reusable Medical Device Sterilization  ISO 17665-1 Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	Demonstrate Sterilization Capabilities	10 <sup>-6</sup> SAL	PASSED
Thermal Profile  AAMI ST77 Containment Devices for Reusable Medical Device Sterilization	Demonstrate Heat Penetration in Load	Minimum temperature of 270° F achieved within 2 minutes and maintained.	PASSED

<p>Transportation Shelf life Study</p> <p>AAMI ST77 Containment Devices for Reusable Medical Device Sterilization</p> <p>Modified ASTM D4169-14 – Standard Practice for performance testing of shipping containers and systems</p>	<p>The purpose was to simulate transportation of the subject device followed by a shelf life study.</p>	<p>No growth 30 days following sterilization loading, unloading and transport.</p>	<p>PASSED</p>
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Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the proposed device is as safe, as effective, and performed as well as or better than the legally marketed predicate devices.