April 30, 2020

Turbett Surgical Inc.
℅ David Furr
Consultant
FDC services
8708 Capehart Cove
Austin, Texas 78733

Re: K200240
Trade/Device Name: Turbett Instrument Pod
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: January 28, 2020
Received: January 31, 2020

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Christopher K. Dugard, M.S.
Assistant Director (acting)
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200240

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. 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 (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 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 that 500mm.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K200240

Date: April 28, 2020

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;
5.	Predicate Device:	Turbett Surgical Container K153025

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 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.

Indications for 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. 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 (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 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 that 500mm.

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

Comparison of Technological Characteristics:

Shown below is a comparison of the subject device with the predicate device.

Element of Comparison	**510(k) Device:** **T**urbett Instrument Pod K200240	**Predicate Device:** Turbett Surgical Container K153025	**Comment**
Regulation and Product Classification Code	21 CFR 880.6850 FRG	21 CFR 880.6850 FRG	Same
Indications for 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. 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 (132°C) and exposure time of 4 minutes.	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. The unit is intended to be used in prevacuum steam	Similar

	• 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 that 500mm. Use only uncovered, perforated or wire mesh general delivery trays within the Turbett Instrument Pod.	sterilizers with a prevacuum cycle of 270ºF (132ºC) and exposure time of 4 minutes. Use no more than 3 trays per level or 25 lbs. per tray. The container may be loaded with up to 15 trays and up to 25 lbs. per tray. Validation was done using 3 trays per level and a maximum instrument load of 25 lbs. per tray. The validation load included six 1mm by 500mm lumens and six 3mm by 400mm lumens. The total weight of instruments and trays validated was 375 lbs. Use only uncovered, perforated or wire mesh general delivery trays within the Turbett Surgical Container.	
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”	34”x24”x22”	Similar
Presentation of Device	Very Large Container with transfer cart, 3 sizes.	Very Large Container with transfer cart	Similar
Sterilization Cycle	Prevacuum Steam 4 minute cycle 132ºC	Prevacuum Steam 4 minute cycle 132ºC	Same
Load	TS1500 up to 375 lbs. TS1200 up to 120 lbs. TS1000 up to 100 lbs.	Up to 15 trays at 25 lb each	Similar
Vent to volume ratio	TS1500 – 0.270 TS1200 – 0.269 TS1000 – 0.264	Turbett Surgical Container 0.265	Different
Storage	Up to 30 days	Up to 30 days	Same

Summary of Non-Clinical Testing:

The following testing was conducted to demonstrate whether the device met the acceptance criteria of the standard. Testing of the TS1000 and TS1500 brackets the parameters for the TS1200:

Name of Test/Citation	**Purpose**	**Acceptance Criteria**	**Results**
Pre-Vacuum thermal profile (TS1000, TS1500) ANSI/AAMI ST77:2013 Containment Devices for Reusable Medical Device Sterilization	To demonstrate steady state thermal conditions throughout the containers during processing	Demonstrate various locations within the container can reach and maintain exposure temperature	Pass – All locations at or above exposure temperature
Pre-Vacuum sterilization efficacy (TS1500) ANSI/AAMI ST77:2006 Containment Devices for Reusable Medical Device Sterilization	To validate sterilization efficacy in a 4 minute steam pre-vacuum cycle	Achieve a 10^{-6} SAL	Pass – 10^{-6} SAL demonstrated
Pre-Vacuum sterilization efficacy (TS1000, TS1500) ANSI/AAMI ST77:2013 Containment Devices for Reusable Medical Device Sterilization	To demonstrate drying capability after a 4 minute steam pre-vacuum cycle	Pre/Post weight difference less than 0.2% and no visible moisture after specified drying time	Pass – Units were within weight specifications and visibly dry
Microbial Aerosol Challenge (TS1500) ANSI/AAMI ST77:2013 Containment Devices for Reusable Medical Device Sterilization	To determine microbial barrier properties in maintaining sterility integrity	Demonstrate maintenance of sterility by no growth of internal test coupons following exposure to microbial aerosol	Pass
Protein analysis and Total Organic Carbon Manual and Mechanical Cleaning Methods AAMI TIR30:2011 A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices	To demonstrate effectiveness of manual and mechanical cleaning of the device	Residual protein samples and Total Organic Carbon within test limit	Pass
30 Day Event Related Shelf Life Study (TS1500) ANSI/AAMI ST77:2013 Containment Devices for Reusable Medical Device Sterilization	To demonstrate container contents can be maintained in a sterile state for up to 30 days	Maintain sterility of contents for 30 days	Pass

Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the Turbett Instrument Pod is as safe, as effective, and performed as well as or better than the legally marketing predicate device (K153025).