DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 14, 2016

Turbett Surgical LLC
% David Furr
Principal Consultant
FDC Services
8708 Capehart Cove
Austin, Texas 78733

Re: K153025
Trade/Device Name: Turbett Surgical Container
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: December 14, 2015
Received: December 17, 2015

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153025

Device Name
Turbett Surgical Container

Indications for Use *(Describe)*
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 sterilizers with a prevacuum cycle of 270°F (132°C) and exposure time of 4 minutes. The container may be loaded with up to 15 trays and up to 25 lbs. per tray.

Validation was done using three trays per level and a maximum instrument load of 25 lbs. per tray. The validation load included six 1mm x 500mm lumens and six 3mm x 400mm lumens. The total weight of instruments and trays validated is 375 lbs.

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

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 Pursuant to 21 CFR 807.92

Date: December 14, 2015 **K153025**

1. Submitted By: Turbett Surgical LLC.
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Rochester, NY 14623
585-755-0133

2. Contact: David C. Furr
FDC Services, LLC
8708 Capehart Cove
Austin, Texas 78733
512-906-9654

3. Product: Turbett Surgical Container
Product code: FRG - Class II (21 CFR 880.6850)

4. Common/Trade Name: Sterilization wrap/container

Description:

The Turbett Surgical Container 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 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. Actual expected loads in hospital settings are likely to be less. Sterilized instruments can be stored for up to 30 days within the closed container.

The Turbett Surgical Container 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 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 sterilizers with a prevacuum cycle of 270ºF (132ºC) and exposure time of 4 minutes. The container may be loaded with up to 15 trays and up to 25 lbs. per tray.

Validation was done using three trays per level and a maximum instrument load of 25 lbs. per tray. The validation load included six 1mm x 500mm lumens and six 3mm x 400mm lumens. The total weight of instruments and trays validated is 375 lbs.

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

Technological Characteristics:

The Turbett Surgical Container 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. The validations included thermal profile, sterilization efficacy, and drying in a pre-vacuum steam sterilizer. Sterilized instruments can be stored for up to 30 days within the closed container.

The container is constructed of 304 stainless steel sheet metal on a rigid stainless steel frame. The container opens from the side for easy placement and retrieval of surgical trays. A filter comprised of 2 layers of filter paper and a compressible gasket is placed in the outer door. After use, the filter/gasket is discarded.

The following testing was conducted to establish substantial equivalence and efficacy:

ANSI/AAMI ST77: Containment Devices for Reusable Medical Device Sterilization testing:

- Pre-vacuum thermal profile
- Steam pre-vacuum sterilization efficacy
- Pre-vacuum dry time
- Microbial aerosol challenge
- 30 day shelf-life study

AAMI TIR 30: A Compendium of Processes, Materials, Test Methods and Acceptance Criteria for Cleaning Reusable Medical Devices testing:

- Protein analysis and Total Organic Carbon Manual cleaning methods

ANSI/AAMI HE75: Human Factors Engineering- Design of Medical Devices testing:

- Human factors usability study

Substantial Equivalence:

The Turbett Surgical Container is substantially equivalent to the SCORES Unit Sterilization Container (K110898). Both products have the same indications for use and perform in a similar manner.

Predicate Device Comparison Table

Element of Comparison	**510(k) Device:** Turbett Surgical Container K153025	**Predicate Device:** SCORES Unit K110898	**Explanation of Differences**
Regulation and Product Classification Code	21 CFR 880.6850 FRG	21 CFR 880.6850 FRG	None
Indications for Use	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 sterilizers with a prevacuum cycle of 270ºF (132ºC) and exposure time of 4 minutes. The container may be loaded with up to 15 trays and up to 25 lbs. per tray. Validation was done using three trays per level and a maximum instrument load of 25 lbs. per tray. The validation load included six 1mm x 500mm lumens and six 3mm x 400mm lumens. The total weight of instruments and trays validated is 375 lbs. Use only uncovered, perforated or wire mesh general delivery trays within the Turbett Surgical Container.	The SCORES Sterilization 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 must be used with the SCORES transfer cart, SCORES filters and integrity locks. The unit is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270 degrees and exposure time of 4 minutes. Use no more than 3 trays per shelf or 25 lbs. per tray. The SCORES Unit was tested and validated with rigid instruments containing lumens with an inner diameter of 3.8mm and an overall length of 370mm. Do not use with instruments containing lumens with an inner diameter smaller than 3.8mm and an overall length longer than 370mm. Use only uncovered, perforated or wire mesh general delivery trays within the SCORES Sterilization Container.	No significant differences other than lumen limitation on SCORES unit. Turbett Surgical Container has been validated with smaller diameter/longer length lumens.
Principal Material of Construction	Stainless Steel and aluminum	Stainless Steel	Aluminum is used for dividers and filter panels for lighter weight
Overall Size	34”x24”x22”	33”x36”x21”	Turbett device is more compact. Validated at this size.

Weight of Empty Container	136 lbs.	150 lbs. (approximated)	The Turbett device is not as heavy as the comparison.
Presentation of Device	Very Large Container with transfer cart	Very Large Container with transfer cart	None
Sterilization Method	Steam autoclave	Steam autoclave	None
Sterilization Cycle	Prevacuum Steam 4 minute cycle	Prevacuum Steam 4 minute cycle	None
Temperature of Sterilization Cycle	270ºF (132ºC)	270ºF (132ºC)	None
Load	Up to 15 trays at 25 lb each	Up to 12 trays at 25 lb each	Turbett container holds slightly more trays. System has been validated at this load.
Number of Perforations	905 holes 0.74 inches diameter (398.2 square inches)	144 holes 1 inch diameter (113.76 square inches)	The vent to volume ratio for the Turbett device allows for better steam penetration.
Storage	Up to 30 days	Up to 30- days	None

Conclusion:

The performance testing data for the subject device (Turbett Surgical Container) demonstrates it is substantially equivalent to the predicate device (K110898). Testing and performance evaluations demonstrate that the product meets specifications and validation requirements.