March 15, 2019

THINK Surgical Inc.
% George Prendergast
Manager of Regulatory Affairs
THINK Surgical, Incorporated
47201 Lakeview Blvd.
Fremont, California 94538

Re: K180127
Trade/Device Name: TCAT® THA Instrument Tray Set
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: February 13, 2019
Received: February 14, 2019

Dear George Prendergast:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K180127

Device Name
TCAT® THA Instrument Tray Set

Indications for Use *(Describe)*
The THINK Surgical TCAT® THA Instrument Tray Set is intended to protect, organize, and deliver to the surgical field TCAT tools, instruments and accessories. The trays allow sterilization of tools, instruments and accessories, and maintain sterility of the enclosed devices until used. The trays are wrapped with an FDA-cleared sterilization wrap during the pre-vacuum autoclave sterilization process.

Table 1 lists the THINK Surgical compatible devices:

Table 1: THINK Surgical Compatible devices

Intended Instrument Tray Set Contents	Description
TCAT General Instruments, Tools and Accessories	Instruments, tools and accessories intended for general use with the TSolution One® Surgical System (TCAT)
TCAT THA Instruments, Tools, and Accessories	Instruments, tools and accessories intended for THA use with the TSolution One® Surgical System (TCAT)

Table 2 lists the sterilization parameters under which the TCAT® THA Instrument Tray Set was validated:

Table 2: Sterilization Parameters

Cycle	Cycle Temperature	Exposure Time	Dry Time
Pre-vacuum	132°C (270°F)	4 minutes	45 minutes

Table 3 provides a description of the TCAT® THA Instrument Tray Set (107985):

Table 3: Description of the TCAT THA Instrument Tray Set

Tray Name	Intended Instrument Tray Set Contents	Dimensions, L x W x H (inches)	Weight
TCAT® Base Instrument Tray PN 107735	TCAT general use instruments, tool and accessories	20 x 9.8 x 4.5	Unloaded: 14.21lbs. Loaded: 17.33lbs.
TCAT® THA Instrument Tray PN107736	Instruments, tools and accessories for THA only	20 x 9.8 x 4.5	Unloaded: 14.39lbs. Loaded: 19.50lbs.

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 of K180127

Submitter Name:	THINK Surgical, Inc.
Submitter Address:	47201 Lakeview Blvd., Fremont, CA 94538
Contact Person:	George J. Prendergast
Phone Number:	(510) 249-2323
Fax Number:	(510) 249-2396
Date Prepared:	March8, 2019
Device Trade Name:	TCAT ®THA Instrument Tray Set
Device Common Name:	Sterilization Cassettes, Instrument Tray, Sterilization Tray, Instrument Delivery System
Classification Name:	Sterilization wrap,
Product Code	KCT
Regulation Number:	21 CFR 880.6850
Predicate Device:	Intuitive Surgical® Instrument and Accessory Sterilization Trays (K072211)

Device Description:
The TCAT THAT Instrument Tray Set is intended only for use with TSolution One® Surgical System instruments, tools and accessories. These trays are used to enclose and hold the instruments, tools, and accessories in an organized manner during the sterilization process and subsequent storage and transportation to and from the surgical suite. The trays are designed to fit any standard autoclave and are constructed primarily of anodized aluminum meeting biocompatibility requirements and compatible with repeated steam sterilizations. The trays have perforations to facilitate sterilant penetration, evacuation, and drying. Since the trays are perforated, an FDA cleared sterilization wrap must be used to maintain sterility of the contents.

The trays have the same size and same basic configuration: a rectangular base with latchable lid. The trays have perforations with an evenly distributed hole pattern on the lid, bottom, and sides to allow sterilant penetration. The bottom surface and interior shelves of the trays contain stanchions designed to separately hold each individual instrument, tool, and accessory for effective sterilant exposure, evacuation and drying during the entire duration of the sterilization process, as well as ease of locating each instrument when placing in or removing from the tray.

The sterilization trays have been tested for use only with THINK Surgical instruments, tools and accessories for a sterilization cycle of pre-vacuum steam sterilization at 132 °C,

4 min cycle with 45-minute dry time.

The type and maximum number of instruments, tool and accessories for each of the trays listed above are as follows:

TCAT® Base Tray (Tray 1) Top		
Part Number	Description	Quantity
103426	Cutter Motor	1
106298-04	Digitizer Ball Probe	1
106382	Digitizer Probe Hub	1
103593	Recovery Marker Installation Tool	1
102940	Cutter Verification Gauge Set	1
103636	Cutter Wrench Set	1
105716	Wrench, Hex, 2.5mm	1
103279	Wrench, Hex 8mm	1
101884	Wrench, T-handle, Square, 8mm	1
104948	BMM Probe Assembly	1
Hospital Supplied	Fixation Clamp, Ø4-5mm pin/Ø8mm rod	2

TCAT® Base Tray (Tray 1) Bottom		
Part Number	Description	Quantity
103205	Fixation Arm, Straight	1
106219	Fixation Adapter Rod, Right-Angle, 4 inch	1
103414	Swivel Block	1
100086	Wrench, Open End, 1-1/8 inch	1
103384	Cutter Motor Cable	1

TCAT® THA Application Tray (Tray 2) Top		
Part Number	Description	Quantity
105653	Cutter Bearing Sleeve, 244mm	1
102613	Recovery Marker, Tack Ø1.5 x 11mm	1
102709	Cutter Ball Probe, 276mm	1
102862-NS	Cutter, Flat, Ø8.25x268mm	1
106298-03	Digitizer Percutaneous Probe	1
107720	Recovery Marker, Groove, Ø4x125mm	2
105734	Cuter, Ball, Ø6x268mm	1
107719	Recovery Marker, Divot, Ø4x70mm	1
Hospital Supplied	Fixation Screw, Self-Drilling, Ø5x150mm	3

TCAT® THA Application Tray (Tray 2) Bottom		
Part Number	Description	Quantity
107645	Cutter Drive Assembly	1
105751	Impactor Coupler Assembly, Magnetic	1
107667	Impactor, Acetabular Cup, 010	1
107666	Reamer Driver, Acetabular Cup, 001	2
107642	Arm Tool Coupler	1

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Predicate Device:
The TCAT® THA Instrument Tray Sets are similar to the Intuitive Surgical® Instrument Accessory Trays, K072211.

Technological Characteristics Comparison:

Table 4 provides a comparison of technological characteristics and principles of operation between the TCAT THA Instrument Tray Set System and its predicate devices.

Table 4:Technological Characteristics Comparison Table

Feature	**TCAT® THA Instrument Tray Set (Subject Device**	**Intuitive Surgical® Instrument Accessory Trays, K072211**	**Comparison**
Intended Use	A sterilization tray is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device.	A sterilization tray is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device.	Same

Load Contents	**TCAT General Instrument, Tools and Accessories:** Instruments, tools and accessories intended for general use with the TCAT Surgical System **TCAT THA, Instruments Tools and Accessories:** Instruments, tools and accessories intended for THA use with the TCAT Surgical System	**Intuitive Surgical EndoWrist Instruments:** DaVinci and DaVinci S families of 8mm and 45mm Endo Wrist Instruments **Intuitive Surgical Reusable Accessories:** DaVinci and Davinci S families of 8mm and 5mm accessories including canulae, obturators, cannula mounts, sterile adapters, etc.	Different
Contents Maximum Load	Medical devices/instruments weighing a maximum of 17.33lbs for TCAT base instrument tray and weighing a maximum of 19.50lbs for the THA instrument tray. .	Medical devices/instruments weighing a maximum of 1lbs for Endo Wrist instrument tray and weighing a maximum of 7lbs for DaVinci and Davinci S trays.	Similar
Design Characteristics			
Device Composition	Base, lift out tray, lid	Base, lid	Similar
Inserts	Yes	Yes	Same
Handles	Yes	Yes	Same
Latches	Yes	Yes	Same
Reusable	Yes	Yes	Same
Materials			
Lid/base/lift out tray, not including inserts	Aluminum	Aluminum	Same
Inserts	Silicone, aluminum, stainless steel, nylon	-	-
Latch	Stainless steel	-	-

Assembled Dimensions	20” x 9.8” x 4.5”	24.1” x 9.7” x 5.5”		Similar
Max load weight	17lbs for TCAT base tray 19.5lbs for THA instrument tray	21lbs.		Similar
Sterilization				
Percent of surface perforations for both subject devices:		Percent of surface perforations for the predicate device:		
-lid -base -lift out tray	21% 19% 22%	-lid, base	-	-
Sterilization Method	Pre-vacuum (Steam)	Pre-vacuum (Steam)		Same
Cycle Temperature	132°C (270°F)	132°C (270°F)		Same
Cycle Time	4 minutes	4 minutes		Same
Drying time	45 minutes	30 minutes		Similar

The TCAT® THA Instrument Tray Sets were found to be similar to the predicate. Three fundamental similarities are:

1. Basic design: Both the TCAT THA Instrument Trays and the predicate have a basic lid/base design with latches, handles, perforations, and contoured inserts or sections for containing items for sterilization, storage, and transport. General size, shape, weight, and materials are not identical but are similar.

2. Fundamental Technology: The TCAT THA Instrument Tray Sets and the predicate allow the sterilant (steam) to penetrate and render its contents sterile by relying on surface perforations.

Primary differences are related to size, shape, intended contents, surface perforations, and appearance.

Summary of Non-Clinical Testing:

Table 5 summarizes the non-clinical performance testing of the TCAT® THA Instrument Tray Sets:

- Sterilization Efficacy
- Packaging
- Cleaning
- Biocompatibility

Table 5: Summary of Non-Clinical Performance Testing

Non-Clinical Performance Testing	**Purpose**	**Results**
Sterilization Efficacy (ISO 17665-1: 2006 Sterilization of health care products-Moist Heat Part 1 Requirements for the development, validation and routine control of sterilization process for medical devices.)	Demonstrate sterilization efficacy of the TCAT THA Instrument Tray Sets containing the maximum inoculated load. .	The test resulted in no growth and six-log reduction at the half-cycle for both devices

	of the indicator organism.	
Packaging (ASTM D4169-16 Standard Practice for Performance Testing in Shipping Containers and Systems)	Demonstrate that the THINK Surgical TCAT® THA Instrument Tray Set was evaluated with maximum load, wrapped according to use instructions and in the shipping configurations according to a shipping validation test.	The results for both trays indicate packaging endpoints were met.
Cleaning (FDA. 2015.Guidance for Industry and FDA Staff-Processing/Reprocessing Medical Devices in Health Care Settings: Validation and Labeling)	Demonstrate that that the cleaning instructions for the TCAT THA Instrument Tray Set are valid.	The results for both tray indicated cleaning endpoints were met.
Biocompatibility (ISO 10993-5:2009 Cytotoxicity Test)	Demonstrate that the TCAT THA Instrument Tray Set is biocompatible.	Under the conditions of the test, the device extract was not cytotoxic.

Conclusions

The conclusions drawn from the nonclinical that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device Intuitive Surgical® Instrument and Accessory Sterilization Trays (K072211).