December 20, 2021

THINK Surgical, Inc.
George Prendergast
Manager, Regulatory Affairs
47201 Lakeview Boulevard
Fremont, California 94538

Re: K203468
Trade/Device Name: TCAT® TKA Instrument Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: November 12, 2021
Received: November 15, 2021

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/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,

Clarence W. Murray, III, PhD
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203468

Device Name

TCAT® TKA Instrument Tray

Indications for Use *(Describe)*

The THINK Surgical TCAT® TKA Instrument Tray is intended to protect, organize and deliver to the surgical field TCAT® tools, instruments and accessories. The tray allows sterilization of TCAT® tools, instruments and accessories and maintains sterility of the enclosed devices until used. The tray is wrapped with an FDA-cleared sterilization wrap during the pre-vacuum autoclave sterilization process.

[See the following page for THINK Surgical compatible devices, sterilization parameters and description of the TCAT® TKA Instrument Tray].

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.

FORM FDA 3881 (CONTINUED)

The following is the continuation of FORM FDA 3881 for the TCAT® TKA Instrument Tray Indications for Use

Table 1 lists the lists the THINK Surgical compatible devices:

Table 1: Intended Instrument Tray Contents

Intended instrument Tray Contents	Description
TCAT General Instruments, Tools and Accessories	Instruments, tools and accessories intended for general use with the TSolution One® Total Knee Application (TCAT® component)
TCAT TKA Instruments, Tools, and Accessories	Instruments, tools and accessories intended for TKA use with the TSolution One® Total Knee Application (TCAT® component)

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

Table 2: Sterilization Parameters

Cycle	Cycle Temperature	Exposure Time	Dry Time
Pre-vacuum	132°C (270°F)	4 minutes	60 minutes

Table 3 provides a description of the TCAT® TKA Instrument Tray (109200):

Table 3: Dimensions and Weights

Tray Name	Dimensions (inches) L x W x H	Weight (lbs.)	
		Unloaded:	Loaded
TCAT® TKA Instrument Tray	21.2” x 10.0” x 4.9”	11.0lbs.	24.0lbs.

510(k) SUMMARY

This summary of 510(k) is submitted in accordance with the requirements of 21CFR 807.92

Applicant Information:

Owner Name:	THINK Surgical, Inc.
Address:	47201 Lakeview Blvd. Fremont, CA 94538
Phone:	510-376-3834
Fax	510-249-2396
Establishment Registration Number:	3000719653
Contact Person:	George J. Prendergast
Date Prepared:	December 20, 2021

Device Information:

Classification:	Class II
Trade Name:	TCAT® TKA Instrument Tray
Common Name:	Sterilization Wrap
Classification Name:	Sterilization Wrap
Regulation Number:	21 CFR 880.6850
Classification Code:	KCT

Predicate Device:
TCAT® TKA Instrument Tray Set cleared via K200632.

Device Modifications:

The changes to the predicate device allow tools, instruments and accessories to be utilized during a total knee arthroplasty (TKA) procedure. The modifications to this device are there is one tray with a lift out tray which contains tools, instruments and accessories for a total knee arthroplasty, the addition of a silicone mat ('utility area'), and the addition of a 13mm Recovery Marker holder.

Device Description:

The TCAT® TKA Instrument Tray is intended only for use with TSolution One® Total Knee Application instruments, tools and accessories. This tray is 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 tray is designed to fit any standard autoclave and is constructed primarily of anodized aluminum. The tray is compatible with repeated steam sterilizations. The tray has perforations to facilitate sterilant penetration, evacuation and drying. Since the tray is perforated, an FDA-cleared sterilization wrap must be used to maintain sterility of the contents.

The tray has the basic same size and a minor configuration change to the predicate device: a rectangular base with a latchable lid and a lift out tray. The tray has perforations with an evenly distributed hole pattern on the lid, bottom, and sides to allow sterilant penetration. The bottom tray surface and lift out tray surface contain stanchions designed to separately hold each individual instrument, tool and accessory for effective sterilant exposure, sterilant evacuation and drying during the entire duration of the sterilization process, as well as ease of locating each instrument when placing in or removal from the tray. The lift out tray contains a silicone mat which may used to sterilize additional THINK Surgical part.

The instrument tray has been tested only with THINK Surgical instruments, tools and accessories for a 4 minute sterilization cycle of pre-vacuum steam sterilization at 132°C, with a 60 minute dry time. While reuseable, these trays will not be serviced or repaired. The type and maximum number of instruments, tools and accessories included in the tray follow:

TCAT® TKA Instrument Tray (Top Tray)		
Part Number	**Description**	**Quantity**
109150	Cutter, Flat, Ø6.2x134mm	1
107937	Cutter, Ø2.0x148mm	1
107974	Cutter Ball Probe, 139mm	1
104948	BMM Probe Assembly	2
106382	Digitizer Probe Hub	1
109189	Fixation Pin, Self-Drilling, Ø4x150mm	2
107720	Recovery Marker, Groove, Ø4x125mm	2
106298-03	Digitizer Percutaneous Probe	1
106298-04	Digitizer Ball Probe	1
103593	Recovery Marker Installation Tool	1
103297	Wrench, Hex, 8mm	1
101888	Wrench, T-Handle, Square, 8mm	1
109195	Recovery Marker, Tack, Ø2.0x13mm	2

TCAT® TKA Instrument Tray (Lift Out Tray)		
Part Number	**Description**	**Quantity**
109066	Swivel Clamp	2
103450	Fixation Adapter Rod, Straight	2
109190	Fixation Clamp, Ø4mm Pin / Ø8mm Rod	2
109142	Cutter Motor	1
105745	Cutter Motor Assembly	1
107642	Arm Tool Coupler	1
108181	Goniometer	1
103205	Fixation Arm, Straight	2
103384	Cutter Motor Cable	1
107720	Recovery Marker, Groove, Ø4x125mm	2

Indications for Use:

The THINK Surgical TCAT® TKA Instrument Tray is intended to protect, organize, and deliver to the surgical field TCAT tools, instruments and accessories. The tray allows sterilization of TCAT® tools, instruments and accessories and maintains sterility of the enclosed devices until used. The tray is wrapped with an FDA-cleared sterilization wrap during the pre-vacuum autoclave sterilization process.

Table 1 lists the lists the THINK Surgical compatible devices:

Table 1: Intended Instrument Tray Contents

Intended instrument Tray Contents	Description
TCAT General Instruments, Tools and Accessories	Instruments, tools and accessories intended for general use with the TSolution One® Total Knee Application (TCAT® component)
TCAT TKA Instruments, Tools, and Accessories	Instruments, tools and accessories intended for TKA use with the TSolution One® Total Knee Application (TCAT® component)

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

Table 2: Sterilization Parameters

Cycle	Cycle Temperature	Exposure Time	Dry Time
Pre-vacuum	132°C (270°F)	4 minutes	60 minutes

Table 3 provides a description of the TCAT® TKA Instrument Tray (109200):

Table 3: Dimensions and Weights

Tray Name	Dimensions (inches) L x W x H	Weight (lbs.)	
		Unloaded	Loaded
TCAT® TKA Instrument Tray	21.2” x 10.0” x 4.9”	11.0lbs.	24.0lbs.

Technological Characteristics:

The modified device, the THINK Surgical TCAT® TKA Instrument Tray is the same as the predicate device which was previously cleared under K200632 in that it:

- incorporates the same basic design and has similar design features such as inserts, handles and latches
- incorporates the same materials such as aluminum, nylon, silicone and stainless steel
- is packaged the same as the predicate device
- has the same sterilization parameters as the predicate device

Comparison of Technological and Performance Characteristics
Three fundamental characteristics are the same between the subject device and predicate devices:

1. **Basic design:** Both the TCAT® TKA Instrument Tray and the predicate device have a basic lid/tray design with latches, handles, perforations, and contoured inserts or sections for containing items for sterilization, storage and transport. General size, shape, and weight of both the subject device and predicate device are similar. The materials of the subject device and the materials of the predicate device are the same.
2. **Role in sterile barrier system:** The TCAT® TKA Instrument Tray and the predicate device must be wrapped with an FDA-cleared sterilization wrap to maintain sterility. Neither the subject device nor the predicate contains gaskets, valves or filters.
3. **Fundamental technology:** The TCAT® TKA Instrument Tray and the predicate device allow the sterilant (steam) to penetrate and render its contents sterile by relying on surface perforations.

The following tables provide a comparison of technological characteristics between the subject device and the predicate device (Table 4) and a summary of non-clinical performance testing (Table 5).

Table 4: Comparison of Technological Characteristics Between the Subject Device and the Predicate Device

Characteristic	TCAT® TKA Instrument Tray (Subject Device)	TCAT® TKA Instrument Tray Set (Predicate Device)	Comparison
510(k) number	K203468	K200632	
Manufacturer	THINK Surgical Inc.	THINK Surgical Inc.	
Intended Use	The THINK Surgical TCAT® TKA 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.	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.	**Same**
Intended Instrument Tray Set Contents Maximum Load	Medical devices/ instruments weighing no less than 11.0lbs-24.0lbs. total including the weight of the trays.	Medical devices/ instruments weighing no less than 14.21lbs-14.39lbs. total including the weight of the trays.	**Similar**

Characteristic	TCAT® TKA Instrument Tray (Subject Device)	TCAT® TKA Instrument Tray Set (Predicate Device)	Comparison
510(k) number	K203468	K200632	
Manufacturer	THINK Surgical Inc.	THINK Surgical Inc.	
Intended Instrument Tray Contents	**TCAT® General Instrument, Tools and Accessories:** Instruments, tools and accessories intended for general use with the TCAT® Total Knee Application. **TCAT® TKA Instruments, Tools and Accessories:** Instruments, tools and accessories intended for use with the TCAT® TSolution One® Total Knee Application.	**TCAT® General Instrument, Tools and Accessories:** Instruments, tools and accessories intended for general use with the TCAT® Total Knee Application. **TCAT® TKA Instruments, Tools and Accessories:** Instruments, tools and accessories intended for use with the TCAT® TSolution One® Total Knee Application.	**Similar**
Design Characteristics			
Device Composition	Single tray with a lift out tray, lid	Base tray, Accessories tray, each with a lift out tray, lid	**Similar**
Inserts	Yes	Yes	**Same**
Handles	Yes	Yes	**Same**
Latches	Yes	Yes	**Same**
Reusable	Yes	Yes	**Same**
Materials			
Single tray with a lift out tray, lid, not including inserts	Aluminum	Aluminum	**Same**
Inserts	Silicone, aluminum, stainless steel, nylon	Silicone, aluminum, stainless steel, nylon	**Same**
Latch	Stainless steel	Stainless steel	**Same**
13mm Recovery Marker Holder	Polymer Polyphenylsulfone, Polypropylene Homopolymer or Polypropylene Polymer	Not contained in the predicate device	**Different**
Silicone Mat	Silicone	Not contained in the predicate device	**Different**
Assembled Dimensions			
Assembled Dimensions	21.2” x 10.0” x 4.9”	20” x 9.8” x 4.5”	**Similar**
Max Load Weight			
Weight containing max load	24.0lbs.	19.5lbs.	**Similar**

Characteristic	TCAT® TKA Instrument Tray (Subject Device)	TCAT® TKA Instrument Tray Set (Predicate Device)	Comparison
510(k) number	K203468	K200632	
Manufacturer	THINK Surgical Inc.	THINK Surgical Inc.	
Sterilization			
Percent of surface perforations			
-lid -bottom tray -lift out tray	21% 13% 19%	21% 19% 22%	**Similar**
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	60 minutes	45 minutes	**Different**

Non-Clinical Performance Testing

Table 5 summarizes the non-clinical performance testing of the TCAT® TKA Instrument Tray Set:

- Sterilization Efficacy
- Shipping/Packaging
- Handle Strength Testing
- Verification of Instrument Tray Product Requirements by Inspection and Analysis
- Verification of Instrument Tray Product Requirements by Lab Test

Table 5: Summary of Non-Clinical Performance Testing

Non-Clinical Performance Testing	Purpose	Results
Sterilization Efficacy	To verify the sterilization efficacy, the TCAT® TKA Instrument Tray contained the maximum load and was inoculated with biological indicators placed in areas of the tray deemed to be most difficult for sterilant (steam) to penetrate. Following inoculation, the tray was wrapped in an FDA-cleared sterilization wrap. The results indicated that the BI Overkill method provided a six-log reduction of the indicator organism. **Standard Followed**: *ANSI/AAMI/ISO 14937:2013 – Sterilization of Healthcare Product – General Requirements for Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices*	PASS
Shipping/Packaging	The TCAT® TKA Instrument Tray was evaluated with maximum load and configured in the shipping configuration according to a shipping validation test. The results indicate packaging requirements were met. **Standard Followed:** *ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems*	PASS

Non-Clinical Performance Testing	Purpose	Results
Handle Strength Testing	The TCAT® TKA Instrument Tray handle strength was evaluated. **Standard Followed**: *ASTM ST77:2013, Containment Devices for Reusable Medical Device Sterilization*	PASS
Verification of Instrument Tray Product Requirements by Inspection and Analysis	The method of verification was to visually inspect the instrument tray per specifications and inspect and analyze documents listed in the protocol to identify the design outputs. The design outputs were then verified against corresponding product requirements. **Standard Followed:** *THINK Surgical developed specification*	PASS
Verification of Instrument Tray Product Requirements by Lab Test	The method of verification was physical, non-destructive testing of the instrument tray to verify design outputs against corresponding product requirements. **Standard Followed:** *THINK Surgical developed specification*	PASS

Clinical and Animal Testing
No clinical or animal testing were required.

Conclusion
The conclusions drawn from the nonclinical tests demonstrate that the subject device in 510(k) submission K203468, the TCAT® TKA Instrument Tray, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared in K200632.