April 8, 2020

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

Re: K200632
Trade/Device Name: TCAT® TKA Instrument Tray Set
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: March 9, 2020
Received: March 10, 2020

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,

For Christopher K. Dugard, MS
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

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)*

K200632

Device Name
TCAT® TKA Instrument Tray Set

Indications for Use *(Describe)*

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.

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

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 set contents

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 TKA Instruments, Tools, and Accessories	Instruments, tools and accessories intended for TKA use with the TSolution One® Surgical System (TCAT®)

Table 2 lists the sterilization parameters under which the TCAT® TKA 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® TKA Instrument Tray Set (109154):

Table 3: Dimensions and weights

Tray Name	Dimensions (inches) L x W x H	Weight (lbs)	
		Unloaded:	Loaded
TCAT® TKA Base Tray PN 107735	20 x 9.8 x 4.5	14.21lbs.	17.33lbs.
TCAT® TKA Application Tray PN 107737	20 x 9.8 x 4.5	7.5lbs.	18.0lbs.

SECTION 6

K200632 510(k) SUMMARY

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

Applicant Information:

Owner Name:	THINK Surgical, Inc.
Address:	47201 Lakeview Blvd. Fremont, CA 94538
Phone:	510-249-2337
Fax	510-249-2396
Establishment Registration Number:	3000719653
Contact Person:	George J. Prendergast
Date Prepared:	March 09, 2020

Device Information:

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

Predicate Device:
TCAT® THA Instrument Tray Set cleared via K180127.

Device Modification:
The changes to the predicated device allow tools, instruments and accessories to be utilized during a total knee arthroplasty (TKA) procedure. The only modification to this device is one tray set (the Application Tray Set) contains new tools, instruments and accessories for a total knee arthroplasty replace those tools instruments and accessories which were included in the TCAT® THA Instrument Tray Set (the predicate device).

Device Description:
The TCAT® TKA Instrument Tray Set is intended only for use with TSolution One® Total Knee Application 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 are 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 of the predicate device: a rectangular base with a 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 removal from the tray.

The sterilization trays have 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 45 minute dry time. While reuseable, these trays will not be serviced or repaired. The type and maximum number of instruments, tools and accessories for each of the trays follow:

TCAT® TKA 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	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
Hospital Supplied	Fixation Clamp, Ø8mm rod/Ø8mm rod	1
Hospital Supplied	Fixation Clamp, Ø3-4mm pin/Ø5mm rod	1

TCAT® TKA 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® TKA Application Tray (Tray 2 top)		
Part Number	**Description**	**Quantity**
106219	Fixation Adapter Rod, Right Angle	1
104948	BMM Probe Assembly	1
106825	Spiked Disk, Femoral Epicondylar Clamp	2
102613	Recovery Marker, Tack, Ø1.5x11mm	2
106413	Cutter Bearing Sleeve, 120mm	1
106298-03	Digitizer Percutaneous Probe	1
107720	Recovery Marker, Groove, Ø4x125mm	2
Hospital Supplied	Fixation Pin, Self-Drilling, Ø3x125mm	1
Hospital Supplied	Fixation Pin, Self-Drilling, Ø4x125mm	2
103454-NS	Cutter, Ø2.0x159mm	1
103455	Cutter, Ball Probe, 151mm	1
106428	Cutter, Flat, Ø6.2x144mm	1
103450	Fixation Adapter Rod, Straight	2

TCAT® TKA Application Tray (Tray 2 Bottom)		
Part Number	**Description**	**Quantity**
107714	Cutter Drive Assembly, TKA	1
103206	Fixation Arm, Straight	1
103414	Swivel Block	1
Hospital Supplied	Wrench, Nut Driver, 5mm	1
106824	Clamp, Femoral Epicondylar	1

Indications for 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.

Technological Characteristics Comparison Table
Three fundamental characteristics are the same between the two devices:

1. **Basic design:** Both the TCAT® TKA Instrument Tray Set and the predicate device 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 the same.
2. **Role in sterile barrier system:** The TCAT® TKA Instrument Tray Set and the predicate device must be wrapped with an FDA-cleared sterilization wrap to maintain sterility. Neither the subject device or the predicate contains gaskets, valves nor filters.
3. **Fundamental technology:** The TCAT® TKA Instrument Tray Set 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 Set (Subject Device)	TCAT® THA Instrument Tray Set (Predicate Device)	Comparison
510(k) number	K200632	K180127	
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 Contents	**TCAT® General Instrument, Tools and Accessories:** Instruments, tools and accessories intended for general use with the TCAT® TSolution One® 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® Surgical System. **TCAT® THA Instruments, Tools and Accessories:** Instruments, tools and accessories intended for use with the TCAT® Surgical System.	**Identical**
Intended Instrument Tray Set Contents Maximum Load	Medical devices/ instruments weighing no less than 7.5lbs-18.0lbs. 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**
Design Characteristics			
Device Composition	Base, lift out tray, lid	Base, lift out tray, lid	**Same**
Inserts	Yes	Yes	**Same**

Characteristic	TCAT® TKA Instrument Tray Set (Subject Device)	TCAT® THA Instrument Tray Set (Predicate Device)	Comparison
510(k) number	TBD	K180127	
Manufacturer	THINK Surgical Inc.	THINK Surgical Inc.	
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	Silicone, aluminum, stainless steel, nylon	**Same**
Latch	Stainless steel	Stainless steel	**Same**
Assembled Dimensions	20” x 9.8” x 4.5”	20” x 9.8” x 4.5”	**Same**
Weight containing max load	18.0lbs.	19.5lbs.	**Similar**
Sterilization			
Percent of surface perforations			
-lid -base -lift out tray	21% 19% 22%	21% 19% 22%	**Same**
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	45 minutes	**Same**

Non-Clinical Performance Testing

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

- Sterilization Efficacy
- Packaging
- Cleaning
- Biocompatibility
- Use and Sterile Processing Guide

Table 5: Summary of Non-Clinical Performance Testing

Non-Clinical Performance Testing	Purpose	Acceptance Criteria	Results
Sterilization Efficacy (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)	To verify the TCAT® TKA Instrument Tray Sets containing the maximum load were inoculated with biological indicators placed in areas of the trays deemed to be most difficult for sterilant (steam) to penetrate. Following inoculation, the trays were wrapped in FDA-cleared sterilization wraps. The trays indicated that the BI Overkill method provided a six-log reduction of the indicator organism.	-All biological indicators (BIs) must be incubated for a minimum of 7 days at 55°C-60°C -The positive control for the SAL testing must show characteristic growth of the indicator organism -Valid temperature data must be collected for each product probe location -Temperature probes used during profiling of the test article must be within ±0.5°C of at least one post calibration reference temperature that is representative of the profiling cycles -All directly-inoculated test article components must demonstrate to contain no bacteriostatic properties by showing growth of *G. stearothermophilus* during method suitability testing	PASS
Packaging (ASTM D4169-16 - Standard Practice for Performance Testing of Shipping Containers and Systems)	To verify the TCAT® TKA Instrument Tray Sets were evaluated with maximum load, wrapped according to use instructions and in the shipping configuration according to a shipping validation test. The results indicate packaging requirements were met.	-Is the packaging or parts of the Application Tray damaged -Is the Packaging or parts of the Base Tray damaged -Are the labels and packing list still affixed and legible	PASS
Reprocessing	To verify the TCAT® TKA Instrument Tray Sets were evaluated for cleanability according to the user instructions. The results indicated cleanability requirements were met.	-Observer shall provide each participant with an IFU -Observer shall ask each participant to read the IFU carefully -Observer shall ask each user to simulate the reprocessing steps according to the IFU -Observer shall fill out the data collection sheet -The data collection sheet	PASS

		indicates all reprocessing steps PASS	
Biocompatibility (ANSI/AAMI/ISO 10993-5:2009 - Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity)	To verify the TCAT® TKA Instrument Tray Sets were evaluated for biocompatibility according to ISO 10993-1. The results indicated biocompatibility requirements were met.	MEM Elution Study -Test article meets a passing score of 2 or below; test article is not considered to have a cytotoxic potential	PASS
Use and Sterile Processing Guide	To verify the TCAT® TKA Instrument Tray Sets were evaluated in accordance with the appropriate guidances. The results indicated use and Sterile Processing Guide requirements were met.	-Participant is able to load components in the tray -Participant is able to load components in the tray with the aid of visual indications showing storage location of each instrument -Participant is able to carry one Instrument Tray -Participant is able to load all components in the tray without requiring an additional tool Participant is able to remove all components in the tray without requiring an additional tool	PASS

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

Conclusion
The conclusions drawn from the nonclinical and clinical tests demonstrate that the TCAT® TKA Instrument Tray Set is as safe, as effective, and performs as well as or better than the legally marketed device.