January 6, 2025

THINK Surgical, Inc.
Denise Duchene
Director, Regulatory Affairs
47201 Lakeview Blvd
Fremont, California 94538

Re: K243481
Trade/Device Name: TMINI Miniature Robotic System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 7, 2024
Received: November 8, 2024

Dear Denise Duchene:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243481

Device Name
TMINI® Miniature Robotic System

Indications for Use *(Describe)*
TMINI® Miniature Robotic System is indicated as a stereotaxic instrumentation system for total knee replacement (TKA) surgery. It is to assist the surgeon by providing software-defined spatial boundaries for orientation and reference information to identifiable anatomical structures for the accurate placement of knee implant components.

The robotic device placement is performed relative to anatomical landmarks as recorded using the system intraoperatively and based on a surgical plan determined preoperatively using CT based surgical planning tools.

The targeted population has the same characteristics as the population that is suitable for the implant(s) compatible with the TMINI® Miniature Robotic System.

The TMINI® Miniature Robotic System is to be used with the following knee replacement systems in accordance with the indications and contraindications:
- Enovis™ EMPOWR Knee System®
- Ortho Development® BKS® and BKS TriMax® Knee System
- Total Joint Orthopedics Klassic® Knee System
- United® U2™ Total Knee System
- Medacta® GMK® Sphere / SpheriKA Knee Systems
- Zimmer Biomet Anterior & Posterior Referencing Persona® Knee
- b-ONE MOBIO® Total Knee System
- Maxx Orthopedics Freedom® Total & Titan Knee
- LINK® LinkSymphoKnee System

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

Applicant Information:

Owner Name:	THINK Surgical, Inc.
Address:	47201 Lakeview Blvd., Fremont, CA 94538
Phone number:	408-921-5648
Fax number:	510-249-2396
Establishment Registration Number:	3000719653
Contact Person:	Denise Duchene
Date Prepared:	15 November 2024

Device Information:

Device Classification:	Class II
Trade Name:	TMINI® Miniature Robotic System
Common name:	Orthopedic Stereotaxic Instrument
Classification name:	Stereotaxic Instrument
Regulation number:	882.4560
Product Code:	OLO

Predicate Device:
The TMINI® Miniature Robotic System (TPLAN® Planning Station and THINK Case Manager (TCM)) is substantially equivalent in intended use, Indications for Use, design, materials, technology, operational principles and performance to the predicate, TMINI® Miniature Robotic System, cleared via K243285.

Device Modification:
The purpose of this submission is to introduce modifications to the TPLAN Planning station used with the TMINI® Miniature Robotic System to enhance efficiency and consistency. The TPLAN® Planning Station component of the TMINI® Miniature Robotic System has been modified to improve the segmentation algorithm using a pre-trained and closed machine learning model during the development, enhance DICOM data importing, update the implant display and selection tools, and improve cybersecurity. In addition, we have added the THINK Case Manager (TCM) as a remote method for surgeon review, approval and downloading of approved surgical plans.

Device Description:
The TMINI® Miniature Robotic System like its predicate, the TMINI® Miniature Robotic System consists of three primary components: a three-dimensional, graphical, Preoperative Planning Workstation (TPLAN Planning Station), an Optical Tracking Navigation Console (TNav) and a robotically controlled hand-held tool (TMINI Robot) that

assists the surgeon in preparing the bone for implantation of TKA components. In addition, this submission will add a web-based method for surgeons to review, approve and download approved surgical plans generated on the TPLAN Planning Station.

The TPLAN Planning Station uses preoperative CT scans of the operative leg to create 3D surface models for case templating and intraoperative registration purposes. The Planning Workstation contains a library of 510(k) cleared knee replacement implant(s) available for use with the system. The surgeon can select an implant model from this library. The planner/surgeon can manipulate the 3D representation of the implant in relation to the bone model to optimally place the implant. The surgeon reviews and approves the case plan using either TPLAN or the TCM web-based application once the surgeon is satisfied with the implant selection, location and orientation. The data from the approved plan is written to a file that is used to guide the robotically controlled hand-held tool.

The hand-held robotic tool is optically tracked relative to optical markers placed in both the femur and tibia and articulates in two degrees-of-freedom, allowing the user to place bone pins in a planar manner in both bones. Mechanical guides are clamped to the bone pins, resulting in subsequent placement of cut slots and drill guide holes such that the distal femoral and proximal tibial cuts can be made in the pre-planned positions and orientations, and such that the implant manufacturer's multi-planer cutting block can be placed relative to drilled distal femoral pilot holes. If the surgeon needs to change the plan during surgery, it can be changed intraoperatively.

Intended Use:

The TMINI System (TPLAN Planning Station and TCM) like the predicate TMINI Miniature Robotic System is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

Indications for Use:

The Indications for Use of the TMINI® Miniature Robotic System (TPLAN Planning Station and TCM) and the predicate are the same (See **Table 1**). Both describe the use of a system that uses diagnostic imaging of the patient to allow a surgeon to plan and execute orthopedic total knee procedures. The only difference is that the device, that is the subject of this 510(k) submission, implements a series of incremental modifications to the TPLAN Planning Station and introduces a web-based method for surgeon review, approval and download of surgical plans to enhance system efficiency, consistency and ease of use.

None of the changes made to the predicate, nor the aggregate of all changes, have altered the indications for use, nor have they raised new type of safety or effectiveness questions.

Tables 1 and 2, below identify the substantial equivalence of the TMINI® Miniature Robotic System (TPLAN Planning Station and TCM) to the predicate, TMINI® Miniature Robotic System cleared via K243285.

Table 1: Comparison of Intended Use and Indications for Use

Product	TMINI® Miniature Robotic System (TPLAN Planning Station and TCM)	TMINI® Miniature Robotic System	Conclusion
510(k) number	K243481	K243285	
Manufacturer	THINK Surgical, Inc	THINK Surgical, Inc	
Product Code	OLO	OLO	**SAME**
Regulation	21 CFR 882.4560	21 CFR 882.4560	**SAME**
Intended Use	Intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.	Intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.	**SAME**
Indications for Use	The TMINI® Miniature Robotic System is indicated as a stereotaxic instrumentation system for total knee replacement (TKA) surgery. It is to assist the surgeon by providing software-defined spatial boundaries for orientation and reference information to identifiable anatomical structures for the accurate placement of knee implant components. The robotic device placement is performed relative to anatomical landmarks as recorded using the system intraoperatively and based on a surgical plan-determined preoperatively using CT based surgical planning tools. The targeted population has the same characteristics as the population that is suitable for the implant(s) compatible with the TMINI® Miniature Robotic System. The TMINI® Miniature Robotic System is to be used with the following knee replacement system(s) in accordance with the indications and contraindications: - Enovis™ EMPOWR Knee System® - Ortho Development BKS® and BKS TriMax® Knee System - Total Joint Orthopedics Klassic® Knee System	The TMINI® Miniature Robotic System is indicated as a stereotaxic instrumentation system for total knee replacement (TKA) surgery. It is to assist the surgeon by providing software-defined spatial boundaries for orientation and reference information to identifiable anatomical structures for the accurate placement of knee implant components. The robotic device placement is performed relative to anatomical landmarks as recorded using the system intraoperatively and based on a surgical plan-determined preoperatively using CT based surgical planning tools. The targeted population has the same characteristics as the population that is suitable for the implant(s) compatible with the TMINI® Miniature Robotic System. The TMINI® Miniature Robotic System is to be used with the following knee replacement system(s) in accordance with the indications and contraindications: - Enovis™ EMPOWR Knee System® - Ortho Development BKS® and BKS TriMax® Knee System - Total Joint Orthopedics Klassic® Knee System	**SAME**

Product	TMINI® Miniature Robotic System (TPLAN Planning Station and TCM)	TMINI® Miniature Robotic System	Conclusion
	- United U2™ Knee Total Knee System - Medacta® GMK® Sphere / SpheriKA Knee Systems - Zimmer Biomet Anterior & Posterior Referencing Persona® Knee - b-ONE MOBIO® Total Knee System - Maxx Orthopedics Freedom® Total & Titan Knee - LINK® LinkSymphoKnee System	- United U2™ Knee Total Knee System - Medacta® GMK® Sphere / SpheriKA Knee Systems - Zimmer Biomet Anterior & Posterior Referencing Persona® Knee - b-ONE MOBIO® Total Knee System - Maxx Orthopedics Freedom® Total & Titan Knee - LINK® LinkSymphoKnee System	

Substantial Equivalence:
Both the TMINI® Miniature Robotic System (TPLAN Planning Station and TCM), the subject of this submission, and the predicate device have the same intended use. Both are indicated as a stereotaxic instrumentation system for total knee replacement (TKA) surgery. It is to assist the surgeon by providing software-defined spatial boundaries for orientation and reference information to identifiable anatomical structures for the accurate placement of knee implant components during orthopedic procedures.

The robotic device placement is performed relative to anatomical landmarks as recorded using the system intraoperatively and based on a surgical plan determined preoperatively using CT based surgical planning tools. The difference between the new device and the predicate is that the new device incorporates a series of incremental changes to the TPLAN Planning Station component and adds a web-based tool for review of surgical plans to enhance system efficiency, consistency and ease of use. None of these changes either individually or in the aggregate alter the intended use, Indications for Use, design, materials, technology, or operational principles of the TMINI® Miniature Robotic System and no new questions of safety or effectiveness resulted from the changes.

The Indications for Use of the TMINI® Miniature Robotic System (TPLAN Planning Station and TCM) and the predicate are the same (See Table 1). Both describe the use of a system that uses diagnostic imaging of the patient to allow a surgeon to plan and execute orthopedic total knee procedures. The only difference is that the device, that is the subject of the 510(k) submission, implements a series of incremental modifications to the TPLAN Planning Station and add a web-based application for review, approval and download of approved surgical plans to enhance system efficiency, consistency and ease of use.

Performance testing to verify the function of the subject device was conducted following similar test methods and acceptance criteria to those used for the predicate device. This testing demonstrated that the TMINI® Miniature Robotic System (TPLAN Planning Station and TCM) met all test criteria and specifications. Validation testing, with methods and acceptance criteria similar to that used for the predicate device, was conducted and all test criteria were met.

Biocompatibility information for patient contacting materials and testing for the TMINI® Miniature Robotic System were presented in predicate device submission K232802. There are no material changes to any of the direct patient contact components of the TMINI® Miniature Robotic System as a result of TPLAN Planning Station and TCM modifications included in this submission; therefore, no additional biocompatibility testing was required.

Substantial equivalence in technological characteristic and performance of the TMINI® Miniature Robotic System to the predicate device is outlined in **Table-2** below:

Table-2: Substantial Equivalence

Product	TMINI® Miniature Robotic System (TPLAN Planning Station and TCM)	TMINI® Miniature Robotic System	Conclusion
510(k) number	K243481	K243285	
Manufacturer	THINK Surgical Inc.	THINK Surgical Inc.	
Materials			
• Materials Used	Uses materials with a long history of use in orthopedic procedures or provided biocompatibility data consistent with ISO 10993 requirements	Uses materials with a long history of use in orthopedic procedures or provided biocompatibility data consistent with ISO 10993 requirements	**SAME**
Technological Characteristics			
• Major System Components	Planning, web-based plan review, and robot control software, robotic positioning device, navigation system, reusable and disposable instrumentation	Planning and robot control software, robotic positioning device, navigation system, reusable and disposable instrumentation	**Substantially equivalent**
• Patient Imaging	CT images used to create a 3D model of the bone for surgical planning	CT images used to create a 3D model of the bone for surgical planning	**SAME**
• Preoperative planning workstation	TPLAN three-dimensional preoperative planning workstation	TPLAN three-dimensional preoperative planning workstation	**SAME**
• Surgical planning system	Technician guided surgical planning with surgeon review and approval on a desktop planning station	Technician guided surgical planning with surgeon review and approval on a desktop planning station	**SAME**
• Surgical planning review, approval, and approved plan export or download	Performed by surgeon on either the TPLAN Planning Station or the THINK Case Manager (TCM)	Performed by the surgeon on the TPLAN Planning Station	**Substantially equivalent**
• Bone Marker Arrays for bone registration and tracking	Active markers on femur and tibia mounted onto the bones via an attachment assembly	Active markers on femur and tibia mounted onto the bones via an attachment assembly	**SAME**
• Surgical Exposure	Similar to traditional surgical exposure	Similar to traditional surgical exposure	**SAME**
• Patient/Robot Registration	Preoperatively determined landmarks are compared to intraoperatively identified landmarks to complete patient bone registration	Preoperatively determined landmarks are compared to intraoperatively identified landmarks to complete patient bone registration	**SAME**

Product	TMINI® Miniature Robotic System (TPLAN Planning Station and TCM)	TMINI® Miniature Robotic System	Conclusion
510(k) number	K243481	K243285	
Manufacturer	THINK Surgical Inc.	THINK Surgical Inc.	
• Camera Tracking Technology	Six camera overhead tracking with a wide-angle field of view	Six camera overhead tracking with a wide-angle field of view	**SAME**
• Cut guide positioning	Robotic device places bone pins in the correct plane, then cutguide or drill block is attached to the pins and bone	Robotic device places bone pins in the correct plane, then cutguide or drill block is attached to the pins and bone	**SAME**
• Intraoperative planning changes	Implant position can be fully adjusted, allowing deviation from the intended implant positioning philosophy and implant size	Implant position can be fully adjusted, allowing deviation from the intended implant positioning philosophy and implant size	**SAME**
• Bone Preparation Technique	A surgical saw is used to cut the bone through a cut guide	A surgical saw is used to cut the bone through a cut guide	**SAME**
• Intraoperative Anatomic Measurements	The tracked bone arrays and bone registration data are used to determine the knee flexion angle and varus/valgus laxity	The tracked bone arrays and bone registration data are used to determine the knee flexion angle and varus/valgus laxity	**SAME**
• Gap Balancing	Displays the maximum space in the medial and lateral compartments in millimeters with the knee in extension and in flexion allowing the surgeon to perform gap balancing, if desired	Displays the maximum space in the medial and lateral compartments in millimeters with the knee in extension and in flexion allowing the surgeon to perform gap balancing, if desired	**SAME**
• TKA Component Implantation Technique	Implants are secured to the bone, either with or without cement using standard surgical technique provided by the implant manufacturer	Implants are secured to the bone, either with or without cement using standard surgical technique provided by the implant manufacturer	**SAME**

Product	TMINI® Miniature Robotic System (TPLAN Planning Station and TCM)	TMINI® Miniature Robotic System	Conclusion
510(k) number	K243481	K243285	
Manufacturer	THINK Surgical Inc.	THINK Surgical Inc.	
• Compatible Knee Implant Systems	- Enovis™ EMPOWR Knee System® - Ortho Development® BKS® and BKS TriMax® Knee System - Total Joint Orthopedics Klassic® Knee System - United® U2™ Knee System - Medacta® GMK® Sphere / SpheriKA Knee Systems - Zimmer Biomet Anterior & Posterior Referencing Persona® Knee - b-ONE MOBIO® Total Knee System - Maxx Orthopedics Freedom® Total & Titan Knee - LINK® LinkSymphoKnee System	- Enovis™ EMPOWR Knee System® - Ortho Development® BKS® and BKS TriMax® Knee System - Total Joint Orthopedics Klassic® Knee System - United® U2™ Knee System - Medacta® GMK® Sphere / SpheriKA Knee Systems - Zimmer Biomet Anterior & Posterior Referencing Persona® Knee - b-ONE MOBIO® Total Knee System - Maxx Orthopedics Freedom® Total & Titan Knee - LINK® LinkSymphoKnee System	**SAME**
Performance Testing			
Full System Run Through Testing	Passed	Passed	**SAME**
Cutting Accuracy • Pin & Block Placement Accuracy • Cadaver Lab Validation Testing • System Gap Balance Accuracy	Passed	Passed	**SAME**
User Needs Validation Testing	Passed	Passed	**SAME**
Usability Testing	Passed	Passed	**SAME**
Software Testing	Passed	Passed	**SAME**
***Biocompatibility Testing**			
• Cytotoxicity	*Passed	Passed	**SAME**
• Sensitization	*Passed	Passed	**SAME**
• Intracutaneous Reactivity	*Passed	Passed	**SAME**
• Acute Systemic Toxicity	*Passed	Passed	**SAME**
• Pyrogenicity	*Passed	Passed	**SAME**

* There are no material changes to any of the direct patient contact components of the TMINI® Miniature Robotic System as a result of TPLAN Planning Station and TCM modifications included in this submission; therefore, no additional biocompatibility testing was required.

Risk assessment was performed on the device in accordance with ISO 14971:2019 and THINK Surgical Risk Management procedures. Each change was assessed separately and in the aggregate through risk analysis and appropriate performance testing to

evaluate the impact of the change. Risk analysis resulted in the identification of new instances of risk; however, no new clinical hazards were identified, and no new questions of safety or effectiveness were identified as a result of these changes. The risks identified have been mitigated to acceptable levels and there is no change in the overall risk profile of the device compared to the predicate cleared in K243285.

Conclusion

The TMINI® Miniature Robotic System (TPLAN Planning Station and TCM) is substantially equivalent to the predicate, TMINI® Miniature Robotic System (K243285), in the following ways:

- it has the same intended use,
- it has the same Indication for Use,
- it has the same technological characteristics and operating principles and incorporates the same design and materials.

Performance testing and risk analysis has demonstrated that the performance and risk profile of the TMINI® Miniature Robotic System (TPLAN Planning Station and TCM) is substantially equivalent to that of the predicate device and does not raise any new question of safety and effectiveness.

THINK Surgical Inc. respectfully submits that this filing contains adequate information and data to demonstrate the substantial equivalence of the TMINI® Miniature Robotic System (TPLAN Planning Station and TCM) to the legally marketed TMINI® Miniature Robotic System cleared via K243285.