October 12, 2023

Think Surgical, Inc.
Anand Patel
Manager, Regulatory Affairs
47201 Lakeview Blvd.
Fremont, California 94538

Re: K232802
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: September 8, 2023
Received: September 12, 2023

Dear Anand Patel:

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.

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)*
K232802

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.

It includes a handheld robotic device, an optical sensor navigation system and accessories, software system, surgical instruments and accessories.

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™ Knee Total Knee 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
K232802

Applicant Information:

Owner Name:	THINK Surgical, Inc.
Address:	47201 Lakeview Blvd., Fremont, CA 94538
Phone number:	443-756-9392
Fax number:	510-249-2396
Establishment Registration Number:	3000719653
Contact Person:	Anand Patel
Date Prepared:	08 September 2023

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 (Additional Knee Systems) 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 K230202.

Device Modification:
The purpose of this submission is to add three additional FDA cleared knee implant systems that are compatible with the TMINI™ Miniature Robotic System to the Enovis™ EMPOWR Knee System® that is already cleared for use with the device. The three new implant systems are: the Ortho Development® BKS® and BKS TriMax® Knee System, the Total Joint Orthopedics Klassic® Knee System, and the United® U2™ Knee System. As part of this change the labeling has been modified to show that the Indications for Use of the device has been updated to include compatibility with these three additional knee implant systems.

Device Description:
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.

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). The surgeon can select an implant model from this library and manipulate the 3D representation of the implant in relation to the bone model to place the implant. Once the surgeon is satisfied with the implant location and orientation, the data is written to a file that is used to guide the robotically controlled hand-held tool.

The handheld 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.

Intended Use:
Like the predicate, the 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 only difference between the indications for use of the current device and the predicate is the addition of the three additional knee systems. See Table-1 below.

Table 1: Comparison of Intended Use and Indications for Use

Product	TMINI™ Miniature Robotic System (Additional Knee Systems)	TMINI™ Miniature Robotic System	Conclusion
510(k) number	Subject Device	K230202	
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	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	**Substantially Equivalent** (Adds Compatibility with three additional total knee implant systems)

Product	TMINI™ Miniature Robotic System (Additional Knee Systems)	TMINI™ Miniature Robotic System	Conclusion
	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. It includes a handheld robotic device, an optical sensor navigation system and accessories, software system, surgical instruments and accessories. 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 - United U2™ Knee Total Knee System	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. It includes a handheld robotic device, an optical sensor navigation system and accessories, software system, surgical instruments and accessories. 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®	

Substantial Equivalence:
Both the TMINI™ Miniature Robotic System (Additional Knee Systems), 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 includes compatibility with three additional knee implant systems. None of these changes either individually or in the aggregate alter the intended use, indications for use (other than the addition of the three new implant systems), design, materials, technology, or operational principles of the TMINI™ Miniature Robotic System.

The Indications for Use of the new device and its predicate are identical except for the addition of the three new implant systems to the list of compatible implant systems.

Performance testing to verify the cutting accuracy 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 met all test criteria and specifications. Validation testing, with methods and acceptance criteria similar to that used for the predicate device, was conducted using simulated surgical testing in a cadaver model 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 K230202. There are no material changes to any of the direct patient contact components of the TMINI Miniature Robotic System.

All four of the Guide Blocks for the TMINI™ Miniature Robotic System (Additional Knee Systems) have text printed on the Indirect Patient Contact Surface of the blocks using Pad printing ink. Biocompatibility testing was provided to assess these materials and included: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity and Pyrogenicity. All 5 tests passed the acceptance criteria of the test protocol.

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 (Additional Knee Systems)	TMINI™ Miniature Robotic System	Substantial Equivalence Conclusion
510(k) number	Subject Device	K230202	
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 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	**SAME**
-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**
-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**
-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 adjusted along bone axis only, preserving the intended implant positioning philosophy.	Implant position can be adjusted along bone axis only, preserving the intended implant positioning philosophy.	**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**

Product	**TMINI™ Miniature Robotic System (Additional Knee Systems)**	**TMINI™ Miniature Robotic System**	**Substantial Equivalence Conclusion**
510(k) number	Subject Device	K230202	
Manufacturer	THINK Surgical Inc.	THINK Surgical Inc.	
-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**
-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	- Enovis™ EMPOWR Knee System®	**Substantially Equivalent** (addition of three new implant systems)
Performance Testing			
-Cutting Accuracy Verification	Passed	Passed	**SAME**
-Cadaver Lab Validation 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**

Risk assessment was performed on the device in accordance with ISO 14971:2019 and THINK Surgical Risk Management procedures. The risk assessment was comprised of analysis and mitigation of the risks associated with the addition of three compatible knee implant systems. The risk assessment resulted in the identification of no new clinical hazards. Each of the clinical hazards identified through this risk assessment is a previously documented hazard associated with the use of the TMINI™ Miniature Robotic System. The addition of three new implant systems does not increase the likelihood or severity of these hazards; therefore, the risks associated with the use of the device remain unchanged as compared to the predicate.

Conclusion

The TMINI™ Miniature Robotic System (Additional Knee Systems) is substantially equivalent to the predicate, TMINI™ Miniature Robotic System (K230202), in the following ways: it has the same intended use, 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 (Additional Knee Systems) is equivalent to that of the predicate device. The

TMINI™ Miniature Robotic System (Additional Knee Systems) is as safe and effective as the predicate device and does not raise any new questions of safety and effectiveness; therefore, a determination of Substantial Equivalence is supported.