April 25, 2023

THINK Surgical, Inc.
Meliha Mulalic
VP, Regulatory Affairs and Quality Assurance
47201 Lakeview Boulevard
Fremont, California 94538

Re: K230202
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: January 24, 2023
Received: January 25, 2023

Dear Meliha Mulalic:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K230202

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 system(s) in accordance with the indications and contraindications: Enovis™ EMPOWR 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Applicant Information:

Owner Name:	THINK Surgical, Inc.
Address:	47201 Lakeview Blvd., Fremont, CA 94538
Phone number:	510-249-2337
Fax number:	510-249-2396
Establishment Registration Number:	3000719653
Contact Person:	Meliha Mulalic
Date Prepared:	January 24, 2023

Device Information:

Device Classification:	Class II
Trade Name:	TMINI™ Miniature Robotic System
Common name:	Orthopedic Stereotaxic Instrument
Classification name:	Stereotaxic Instrument
Regulation number:	21 CFR 882.4560
Product Code:	OLO

Predicate Device:

The TMINI™ Miniature Robotic System is substantially equivalent in intended use, fundamental scientific technology and performance to the following legally marketed device in commercial distribution: Rosa Knee System cleared by the FDA through K182964.

Device Description:

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 optimally 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

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

he 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 system(s) in accordance with their indications and contraindications: Enovis™ EMPOWR Knee System®.

Substantial Equivalence:

The TMINI™ Miniature Robotic System, is substantially equivalent to the predicate Rosa Knee System cleared by FDA through K182964. The subject device has the same intended use as the predicate device and substantially equivalent indications for use, materials, technology and operational principles.

Both the TMINI™ Miniature Robotic System and the predicate, Rosa Knee System, consist of three primary components; a planning workstation or online planning application, an optical tracking system and a robotically controlled device that assists the surgeon in preparing the bone for implantation of the TKA components. Both Systems use three-dimensional (3D) preoperative planning software that aids the surgeon in planning the position and orientation of the implant components relative to 3D models of the patient's anatomy. Both the TMINI™ Miniature Robotic System and the predicate, Rosa Knee System, use a robotic device with a tracking array that guides the surgeon in preparing the bone for implantation of the total knee components consistent with the planned surgical procedure.

The tools and accessories that are used to accomplish total knee arthroplasty are the same or substantially equivalent to those used for conventional TKA procedures without robotic control. These include various instrumentation both reusable and disposable: surgical drapes, drills, saw blades, probes, bone pins, and cut and drill guides.

The substantial equivalence of the TMINI™ Miniature Robotic System is supported by equivalence in materials, technology and operational principals, and performance testing which supports the safety and substantial equivalence of the device for use in TKA.

Comparison of Intended Use and Indications for Use

Product	TMINI™ Miniature Robotic System	Rosa Knee System	Conclusion
510(k) number	PENDING	K182964	
Manufacturer	Think Surgical, Inc	Orthosoft Inc. (d/b/a Zimmer CAS)	
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**

Product	TMINI™ Miniature Robotic System	Rosa Knee System	Conclusion
510(k) number	PENDING	K182964	
Manufacturer	Think Surgical, Inc	Orthosoft Inc. (d/b/a Zimmer CAS)	
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. 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 their indications and contraindications: Enovis™ EMPOWR Knee System®.	The Rosa® 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, optionally determined preoperatively using compatible X-ray or MRI based surgical planning tools. It includes a robotic arm, 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 Rosa® Knee System. The Rosa Knee System is to be used with the following fixed bearing knee replacement systems in accordance with their indications and contraindication: NexGen® CR, NexGen CR-Flex, NexGen CR-Flex Gender, NexGen LPS, NexGen LPS-Flex, NexGen LPS-Flex Gender, Persona CR, Persona® CR, Persona PS, Vanguard® CR and Vanguard PS.	**Substantially Equivalent** (1) Both systems have a pre-surgical planning module – while Rosa can also be used intraoperatively without a pre-surgical plan. (2) Both systems use radiographic imaging – TMINI uses CT imaging while Rosa uses either X-ray or MRI imaging. (3) Both systems have a robotic device that assists with surgical preparation - the TMIN robotic device is handheld while the Rosa has a robotic arm. (4) Both devices are used only with their stated compatible implant systems

Comparison of Materials, Technological Characteristics and Performance Testing

Product	TMINI™ Miniature Robotic System	Rosa Knee System	Conclusion
510(k) number	Pending	K182964	
Manufacturer	Think Surgical Inc	Orthosoft Inc. (d/b/a Zimmer CAS)	
Materials			
-Materials Used	Uses materials with a long history of use in orthopedic procedures.	Uses materials with a long history of use in orthopedic procedures.	**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**
-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 via an online review application	**Substantially Equivalent** (Both systems have a surgical planning system – TMINI has a desktop planning station, while Rosa uses an online application)
-Pre-surgical Imaging	CT images used to create a 3D model of the bone for surgical planning	MRI or X-ray used to create 3D model of the bone for pre-operative planning	**Substantially Equivalent** (Both systems use radiographic imaging to create 3D bone models – TMINI uses CT and Rosa uses X-ray or MRI)
-Surgical Exposure	Similar to traditional surgical exposure	Similar to traditional surgical exposure	**SAME**
-Bone Marker Arrays for bone registration and tracking	Active markers on femur and tibia mounted onto the bones via an attachment assembly.	Passive reflective markers on femur and tibia mounted onto the bones via an attachment assembly.	**Substantially Equivalent** (Both systems use bone markers for registration and tracking of motion – TMINI uses active markers, while Rosa uses passive markers)
-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	Rosa Knee System	Conclusion
510(k) number	Pending	K182964	
Manufacturer	Think Surgical Inc	Orthosoft Inc. (d/b/a Zimmer CAS)	
Camera Tracking Technology	Six camera overhead tracking with a wide angle field of view	Two camera sideways tracking with traditional field of view	**Substantially Equivalent** (Both systems provide intraoperative tracking required for robotic control and patient tracking)
-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 a cut guide or drill block in the correct plane, then bone pins are used to secure the guide or block to the bone.	**Substantially Equivalent** (Both systems use robotic control to place the cut guides to execute the TKA procedure – TMINI places the bone pins under robot control and then attaches the cut guide to the pins, while Rosa places the cut guide in the correct plane using the robot arm and then drills the pins to secure the guide)
- Intraoperative planning changes	Implant position can be adjusted along bone axis only, preserving the intended implant positioning philosophy.	Implant position can be fully adjusted, allowing deviation from the intended implant positioning philosophy.	**Substantially Equivalent** (Both systems allow for some degree of intraoperative adjustment of the surgical plan)
-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**
-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	Rosa Knee System	Conclusion
510(k) number	Pending	K182964	
Manufacturer	Think Surgical Inc	Orthosoft Inc. (d/b/a Zimmer CAS)	
Performance Testing			
-Biocompatibility	Passed	Passed	**SAME**
-Cutting Accuracy	Equivalent or better than manual instrumentation < 0.5mm RMSE	Equivalent or better than manual instrumentation < 0.75mm RMSE	**Substantially Equivalent** (See Section 19 for Details)
-Cadaver Lab Validation Testing	Passed	Passed	**SAME** (See Section 19 for Details)
-Software Testing	Passed .	Passed .	**SAME** (See Section 17 for Details)
-Electromagnetic Compatibility and Electrical Safety	Meets IEC Requirements	Meets IEC Requirements	**SAME** (See Section 18 for Details)

Conclusion

The TMINI™ Miniature Robotic System is substantially equivalent to the legally marketed predicate, Rosa Knee System (K182964) in the following ways:

- has the same intended use,
- has substantially equivalent Indications for Use,
- has the same or substantially equivalent materials, technological characteristics and operational principles.

Think Surgical Inc. respectfully submits that this filing contains adequate information and data to demonstrate the substantial equivalence of the TMINI™ Miniature Robotic System to the legally marketed Rosa Knee System (cleared by K182964).