April 1, 2021

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

Re: K210668
Trade/Device Name: TSolution One® Total Knee Application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 4, 2021
Received: March 5, 2021

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, 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)*

K210668

Device Name
TSolution One® Total Knee Application

Indications for Use *(Describe)*

The TSolution One® Total Knee Application is intended for use as a device that uses diagnostic images of the patient acquired specifically to assist the physician with preoperative planning and to provide orientation and reference information during intraoperative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool are used as an alternative to manual planning and resecting techniques for the distal femur and proximal tibia preparation in primary total knee arthroplasty (TKA).

The TSolution One® Total Knee Application is indicated for orthopedic procedures in which resecting techniques used for the distal femur and proximal tibia may be considered to be safe and effective and where references to rigid anatomical structures may be made.

The TSolution One® Total Knee Application is also intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The TSolution One® Total Knee Application facilitates accurate positioning of TKA implants, relative to these alignment axes.

The TSolution One® Total Knee Application is compatible with the following Knee Implant Systems:
- Aesculap Columbus Knee System
- Corin Unity Knee
- DJO Surgical EMPOWR 3D Knee
- DJO Surgical EMPOWR Knee System
- Ortho Development Balanced Knee
- Total Joint Orthopedics Klassic Knee System
- United U2 Knee
- Zimmer Biomet Persona

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.

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:	04 March 2021

Device Information:

Device Classification:	Class II
Trade Name:	TSolution® One Total Knee Application
Common name:	Orthopedic Stereotaxic Instrument
Classification name:	Stereotaxic Instrument
Regulation number:	882.4560
Product Code:	OLO

Predicate Device:
The TSolution® One Total Knee Application is substantially equivalent in intended use, Indications for Use, design, materials, technology, operational principles and performance to the predicate device cleared via K203040.

Device Modification:

The purpose of this submission is to add three more FDA cleared knee implant systems that are compatible with the TSolution® One Total Knee Application to the five knee systems that are already cleared for use with the device. The three new implant systems are: the Ortho Development Balanced Knee, the Total Joint Orthopedics Klassic Knee, and the DJO Surgical® EMPOWR 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.

THINK SURGICAL

Device Description:
Like its predicate, the TSolution One® Total Knee Application is a three-dimensional, graphical, preoperative planning workstation and implementation tool for treatment of patients who require total joint arthroplasty. The device is intended as an alternative to manual template planning and preparation of the bone with patients requiring primary total knee arthroplasty (TKA).

The TSolution One® Total Knee Application consists of TPLAN and TCAT. TPLAN is a three-dimensional (3D) preoperative planning workstation that aids a surgeon in planning the position and orientation of the implant components relative to 3D models of the patient's anatomy. TCAT consists of an electromechanical arm, an arm base including control electronics and computer, a display monitor, operating software, pendant control, and tools and accessories, for the implementation of the preoperative plan. TCAT and TPLAN when used according to the instructions for use, make submillimeter precision bone preparation possible before and during TKA surgical procedures.

Intended Use / Indications for Use:
Like the predicate, the TSolution One® Total Knee Application is intended for use as a device that uses diagnostic images of the patient acquired specifically to assist the physician with preoperative planning and to provide orientation and reference information during intraoperative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool are used as an alternative to manual planning and resecting techniques for the distal femur and proximal tibia preparation in primary total knee arthroplasty (TKA).

The TSolution One® Total Knee Application is indicated for orthopedic procedures in which resecting techniques used for the distal femur and proximal tibia may be considered to be as safe and effective and where references to rigid anatomical structures may be made.

The TSolution One® Total Knee Application is also intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The TSolution One® Total Knee Application facilitates accurate positioning of TKA implants, relative to these alignment axes.

The TSolution One® Total Knee Application is compatible with the following Knee Implant Systems:

- Aesculap Columbus Knee System
- Corin Unity Knee
- DJO Surgical EMPOWR 3D Knee
- DJO Surgical EMPOWR Knee System
- Ortho Development Balanced Knee
- Total Joint Orthopedics Klassic Knee System
- United U2 Knee
- Zimmer Biomet Persona

Substantial Equivalence:
Both the TSolution One® Total Knee Application, the subject of this submission, and the predicate device have the same intended use. Both are intended for use as devices that use diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intraoperative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan. 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 TSolution One Total Knee Application.

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 TSolution One® Total Knee Application 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.

Substantial equivalence in technological characteristic and performance of the TSolution One® Total Knee Application to the predicate device is outlined in the table below:

Product	**TSolution One Total Knee Application**	**TSolution One Total Knee Application**	**Substantial Equivalence Conclusion**
510(k) number	Subject Device	K203040	
Manufacturer	THINK Surgical Inc.	THINK Surgical Inc.	
Technological Characteristics			
-Patient Imaging	CT Scan	CT Scan	**SAME**
-User Controls	Keyboard, mouse, Pendant with mechanically latched Stop Button	Keyboard, mouse, Pendant with mechanically latched Stop Button	**SAME**
-Preoperative planning workstation	TPLAN three-dimensional preoperative planning workstation	TPLAN three-dimensional preoperative planning workstation	**SAME**
-Pre-surgical Plan	CT images used to create a 3D model of the bone, library of FDA cleared components used to develop optimal implant size and location	CT images used to create a 3D model of the bone, library of FDA cleared components used to develop optimal implant size and location	**SAME**
-Surgical Plan Data	High level operative plan based on preoperative plan with predetermined control file developed to control the robotic arm.	High level operative plan based on preoperative plan with predetermined control file developed to control the robotic arm.	**SAME**

Product	**TSolution One Total Knee Application**	**TSolution One Total Knee Application**	**Substantial Equivalence Conclusion**
510(k) number	Subject Device	K203040	
Manufacturer	THINK Surgical Inc.	THINK Surgical Inc.	
-Surgical Exposure	Similar to traditional surgical exposure for the anatomic site	Similar to traditional surgical exposure for the anatomic site	**SAME**
Electromechanical arm to implement pre-surgical plan	TCAT electromechanical arm system implements pre-surgical plan	TCAT electromechanical arm system implements pre-surgical plan	**SAME**
-Patient/Robot Registration	Pinless point to surface registration with mechanical tracking. Percutaneous probe thin enough to make contact via direct puncture through skin.	Pinless point to surface registration with mechanical tracking. Percutaneous probe thin enough to make contact via direct puncture through skin.	**SAME**
-Bone Motion Recovery	Two bone motion recovery markers are used to recover registration after bone motion.	Two bone motion recovery markers are used to recover registration after bone motion.	**SAME**
-Compatible Knee Implant Systems	-Aesculap Columbus Knee System -Corin Unity Knee -DJO Surgical EMPOWR 3D Knee <u>- DJO Surgical EMPOWR Knee System</u> <u>-Ortho Development Balanced Knee</u> <u>-Total Joint Orthopedics Klassic Knee System</u> -United U2 Knee -Zimmer Biomet Persona	-Zimmer Persona™ Knee System -Corin Unity Knee System -Aesculap Columbus Knee System -DJO Surgical® EMPOWR 3D Knee® System -United U2 Knee System	**Substantially Equivalent** (addition of three new implant systems – underlined)
Performance Testing			
-Cutting Accuracy Verification	Passed	Passed	**SAME**
-Cadaver Lab Validation Testing	Passed	Passed	**SAME**
-Software Testing	Passed	Passed	**SAME**

Risk assessment was performed on the device in accordance with ISO 14971:2007 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 TSolution One® Total Knee Application. 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 TSolution One® Total Knee Application is substantially equivalent to the predicate, TSolution One® Total Knee Application (K203040), 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 TSolution One® Total Knee Application (the subject of this submission) are equivalent to those of the predicate device. The TSolution One® Total Knee Application 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.