DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 14, 2016

Think Surgical Inc.
% Mr. Glen Emelock
Senior Partner
The CRO Group, Inc.
32 Harrison Street
Melrose, Massachusetts 02176

Re: K162195
Trade/Device Name: TSolution One® Cup1 Surgical System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 5, 2016
Received: August 18, 2016

Dear Mr. Emelock:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162195

Device Name
TSolution One® Cup1 Surgical System

Indications for Use *(Describe)*
The TSolution One® Cup1 Surgical System is intended for use as a device that uses 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 preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/ reaming/impacting techniques for femoral canal and acetabular cup preparation in primary cementless total hip arthroplasty (THA) using a posterior approach.

The TSolution One® Cup1 Surgical System is indicated for orthopedic procedures in which the broaching, reaming, and impacting techniques used in primary cementless total hip arthroplasty (THA) using a posterior approach may be considered to be safe and effective and where references to rigid anatomical structures may be made.

The TSolution One® Cup1 Surgical System 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® Cup1 Surgical System facilitates accurate positioning of THA implants, relative to these alignment axes.

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)

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510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter Name:	THINK Surgical, Inc.
Submitter Address :	47320 Mission Falls Court Fremont, CA 94539
Contact Person:	Glen Emelock
Phone Number:	(510) 249-2300
Fax Number:	(510) 249-2396
Date Prepared:	August, 2016
Device Trade Name:	TSolution One® Cup1 Surgical System
Device Common Name:	Stereotaxic Instrument
Classification Name:	Orthopedic Computer Controlled Surgical System, OLO
Regulation Number:	21 CFR 882.4560
Predicate device:	TSolution One™ w/ACG+ Surgical System, K153647
Reason for submission:	Not previously marketed in the USA

Device Description:
The TSolution On® Cup1 Surgical System is a three-dimensional, graphical, preoperative planner and implementation tool for treatment of patients who require a total hip arthroplasty (THA) procedure. This device is intended as an alternative to manual template planning, broaching, reaming and impacting techniques for the preparation of femoral canal and acetabular cup for patients requiring a primary THA procedure. The system consists of the TPLAN™ Preoperative Planning Workstation and TCAT™, a robotic system composed of an electromechanical arm, arm base including control electronics and computer, display monitor, and miscellaneous accessories such as cutters, drapes, irrigation sets, probes, and markers. TPLAN™ and TCAT™ when used according to the instructions for use, make precision femoral canal and acetabular cup preparation possible before and during THA surgical procedures..

Intended Use:
The TSolution One® Cup1 Surgical System is intended for use as a device that uses 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 preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming/impacting techniques for femoral canal and acetabular cup preparation in primary cementless total hip arthroplasty (THA) using a posterior approach.

The TSolution One® Cup1 Surgical System is indicated for orthopedic procedures in which the broaching, reaming and impacting techniques used in primary cementless total hip arthroplasty (THA) using a posterior approach may be considered to be safe and effective and where references to rigid anatomical structures may be made.

The TSolution One® Cup1 Surgical System 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® Cup1 Surgical System facilitates accurate positioning of THA implants, relative to these alignment axes.

Predicate Device:
The TSolution One® Cup1 Surgical System is substantially equivalent to the TSolution One™ w/ACG+ Surgical System, K153647.

Comparison of Technological Characteristics and Principles of Operation:
The TSolution One® Cup1 Surgical System is very similar to the legally marketed predicate in that they share the same intended use and indications, same fundamental scientific technology, same principles of operation and similar technological characteristics and performance data as the predicate device.

Table 1 provides a comparison of technological characteristics and principles of operation between the The TSolution One® Cup1 Surgical System and its predicate devices.

Table 1: Comparison of Technological Characteristics and Principles of Operation

Device	Patient Image Data	Presurgical Plan	Surgical Plan Data	Machine Instructions	Patient/Device Registration Requirement	Robot Electromechanical Arm
TSolution One® w/ACG+ Surgical System	Yes, CT Scan	Yes, Presurgery	Yes, high level operative plan	Yes, Robotic Arm driven by validated control software and hardware	Yes, point to surface registration	Yes, robot with single electromechanical arm and end effector implement control file instructions
TSolution One™ Cup1 Surgical System	Yes, CT Scan	Yes, Presurgery	Yes, high level operative plan	Yes, Robotic Arm driven by validated control software and hardware	Yes, point to surface registration	Yes, robot with single electromechanical arm and end effector implement control file instructions

Any minor differences between the TSolution One® Cup1 Surgical System and its predicate device raise no new questions of safety or effectiveness nor change the device's intended therapeutic effect in comparison to its predicate.

Performance Data:
The TSolution One® Cup1 Surgical System has been evaluated with non-clinical performance testing for the following modifications and or improvements:

- TPLAN Bug Fixes
- TCAT Bug Fixes
- TCAT Instrument Changes
- System User Manuals Changes

Table 2: Verification / Validation Activities

Verification / Validation Activity	Purpose	Results
Software Testing	Verify TPLAN presurgical planning and TCAT surgical system software function as intended to successfully complete THA procedure including Acetabular Cup Guidance	PASS
Support Surgical Instrument Testing	Verify TCAT surgical support instruments function as intended to successfully complete THA procedure including Acetabular Cup Guidance and meet user needs.	PASS

In accordance with the Design Control process, risk analysis was conducted to evaluate the impact of modifications to the predicate instruments. Design verification and design validation testing were conducted on the subject instruments to confirm that the design outputs meet design input requirements and that each instrument is safe and effective for its intended use.

Conclusions
The results of performance testing indicated the device performed within the intended use and the differences between the predicate and the TSolution One® Cup1 Surgical System do not raise any new safety or efficacy issues. Supporting information included in this premarket submission confirms that the TSolution One® Cup1 Surgical System is safe and effective for the intended use and is substantially equivalent to the predicate device.