



Food and Drug Administration
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THINK Surgical Incorporated
% Mr. Glen Emelock
Senior Partner
The CRO Group, Incorporated
32 Harrison Street
Melrose, Massachusetts 02176

October 22, 2015

Re: K150741

Trade/Device Name: TSolution One™ w/ACG Surgical System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OJP, OLO
Dated: October 1, 2015
Received: October 2, 2015

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 Part 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 yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150741

Device Name

TSolution One™ w/ACG Surgical System

Indications for Use (Describe)

The TSolution One™ w/ACG 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™ w/ACG 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™ w/ACG 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™ w/ACG 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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: | March, 2015 |
| Device Trade Name: | TSolution One™ w/ACG Surgical System |
| Device Common Name: | Stereotaxic Instrument |
| Classification Name: | Orthopedic Computer Controlled Surgical System, OJP, OLO |
| Regulation Number: | 21 CFR 882.4560 |
| Predicate device: | TCAT™/TPLAN™ Surgical System, K140585 |
| Reason for submission: | Not previously marketed in the USA |

Device Description:

The TSolution One™ w/ACG 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™ w/ACG 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 w/ACG 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™ w/ACG 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™ w/ACG Surgical System facilitates accurate positioning of THA implants, relative to these alignment axes.

Predicate Device:

The TSolution One™ w/ACG Surgical System is substantially equivalent to the TCAT™/TPLAN™ Surgical System, K140585 and the OrthAlign OrthAlign Plus® System, K140331.

Comparison of Technological Characteristics and Principles of Operation:

The TSolution One™ w/ACG Surgical System is similar to the legally marketed devices listed previously in that they share the same intended use and indications, technological characteristics, principles of operation and performance data as the predicate devices.

Table 1 provides a comparison of technological characteristics and principles of operation between the TSolution One™ w/ACG 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 |
|--------------------------------------|--------------------|------------------|--------------------------------|--|---|---|
| TCAT™/TPLAN™ 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™ 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 |
| OrthAlign OrthAlign Plus® System | Not specified | Yes, Presurgery | Yes, high level operative plan | N/A, surgeon manipulates based on computer module info | Yes, point to surface registration | No |

Any minor differences between the TSolution One™ w/ACG Surgical System and its predicate devices 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™ w/ACG Surgical System has been evaluated with non-clinical performance testing as per Table 2 below for the following modifications and or improvements:

- TPLAN Acetabular Cup Module – prepares surgeon for acetabular cup reaming and impacting
- TCAT Acetabular Cup Module – guides surgeon during acetabular cup reaming and impacting
- Irrigation Pump Modification – results in improved irrigation of surgical site during bone cutting
- Acetabular Cup Bone Motion Recovery Markers – permits continuation of procedure in event of acetabular cup motion during surgery
- Acetabular Cup Tools – provides reusable surgical instruments facilitating acetabular cup reaming and impacting
- Cutter Motor Controller – provides additional cutter motor control capabilities for future surgical systems
- Direct Drive Z-axis – provides more responsive Z-axis positioning during robot movement
- Load Cell Change – for RoHS compliance
- BMM Cable Change - for improved BMM signal quality

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 |
| Usability Testing | Verify TPLAN presurgical planning and TCAT user interface functions as intended to successfully complete THA procedure including Acetabular Cup Guidance and meet user needs. | PASS |
| Benchtop Accuracy Testing | Verify overall system (TPLAN presurgical planning, and TCAT surgical system) accuracy in meeting specified requirements. | PASS |

| | | |
|-----------------|---|------|
| Cadaver Testing | Validate that the workflow of the TSolution One™ w/ACG Surgical System including THA software as well as tools and accessories in a simulated use environment functions as intended to successfully complete a THA procedure including Acetabular Gup Guidance and meets customer requirements. | PASS |
|-----------------|---|------|

Conclusions

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