

K072806

Page 1 of 2



JAN 24 2008

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**ATTACHMENT 1  
510(K) SUMMARY**

**Submitter:** MAKO Surgical Corp.  
**Address:** 2555 Davie Road, Fort Lauderdale, FL, 33317  
**Phone number:** 954-927-2044 x. 605  
**Fax number:** 954-927-0446  
**Contact Person:** William F. Tapia  
**Date Prepared:** September 28 2007  
**Device Trade Name:** Tactile Guidance System (TGS)  
**Common Name:** Stereotaxic Instrument  
**Classification Name:** Class II  
**Classification #:** 21 CFR 882.4560

**Substantial Equivalence Claimed To:** The TGS is substantially equivalent to the Voyager / Tactile Guidance System - CT (K052851), Uni-Knee Surgetics Navigation System (K062146), Acumen System (K031454, K031337), Vectorvision Uni-Knee (K041899), and Navitrack System-OS Unicondylar Knee Universal (K071714).

**Description:** The TGS is a stereotaxic instrument that includes an optical detector, computer, dedicated instrumentation, operating software, tools and accessories, and the TGS robotic arm. TGS uses patient CT data to assist the physician with presurgical planning and interpretive/intraoperative navigation. The TGS robotic arm, which is an add-on to the Navigation Module, serves as an "intelligent" tool holder or tool guide used by a surgeon for stereotactic guidance during minimally invasive orthopedic surgical procedures. The TGS robotic arm, an electromechanical arm, is passively constrained by software-defined spatial boundaries implemented through the use of the TGS robotic arm and is designed to support a surgeon's preparation of an anatomical site for an orthopedic implant with standard surgical tools such as drills, awls, and 3<sup>rd</sup> party drill systems.

**Summary of Technological Characteristics:** The TGS consists of the following basic components:

1. High Resolution Color Liquid Crystal Display (LCD) Touch Screen Monitor
2. Second High Resolution LCD screen that shows an identical image to the primary touch screen.
3. Uninterruptible Power Supply (UPS)
4. Central Processing Unit (CPU)
5. Isolation Transformer
6. Keyboard and Mouse
7. Optical Detector
8. Operating Room (OR) Cart
9. Foot control panel
10. Tool and accessories – optically tracked surgical tools and accessories
11. TGS robotic arm – tool platform that is connected to the Voyager Navigation Platform to enable passive stereotactic guidance of any cleared standard surgical tool such as 3<sup>rd</sup> party drill systems (e.g., Anspach's eMax (K011444)) to prepare anatomical sites for placement of orthopedic implants in a minimally invasive manner.
12. Voyager software application
13. Linux operating system
14. Software drivers for video grabber, standard computer components (keyboard, mouse, monitor, etc.)
15. Preoperative planning laptop that runs only the preoperative planning portion of the application. Dicom CDs of CT scans with patient data can be loaded and surgical plans can be created on this laptop and downloaded (in an encrypted format) to a USB memory stick to be transferred to the TGS.

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Page 2 of 2



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**Intended Use/Indications for Use:** The Tactile Guidance System is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The Tactile Guidance System is indicated for use in surgical knee procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy. These procedures include:

- Unicondylar knee replacement



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 24 2008

Mako Surgical Corporation  
% Mr. William F. Tapia  
Vice President, RA/QA  
2555 Davie Road  
Ft. Lauderdale, Florida 33317

Re: K072806

Trade/Device Name: Tactile Guidance System (TGS)  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic instrument  
Regulatory Class: II  
Product Code: HAW  
Dated: January 16, 2008  
Received: January 17, 2008

Dear Mr. Tapia:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

Page 2 – Mr. William F. Tapia

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K072806



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ATTACHMENT 2

INDICATIONS FOR USE

510(k) Number (if known): K072806

Device Name: Tactile Guidance System (TGS)

Indications for Use:

The Tactile Guidance System is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The Tactile Guidance System is indicated for use in surgical knee procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy. These procedures include:

- Unicondylar knee replacement

Prescription Use  X

OR

Over-the-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number \_\_\_\_\_

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