K081867

K081867

NOV 25 2008

2555 davie road fort lauderdale, florida 33317 tel 954.927.2044 fax 954.927.0446

EXHIBIT L
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:	June 30 2008
Device Trade Name:	Tactile Guidance System v2.0
Common Name:	Stereotaxic Instrument
Classification Name:	Class II
Classification #:	21 CFR 882.4560

Substantial Equivalence Claimed To: The Tactile Guidance System (TGS) v2.0 is substantially equivalent to the MAKO Surgical's Tactile Guidance System (K072806) and Voyager/Tactile Guidance System-CT (K052851) and Biomet's Acumen™ Surgical Navigation System (K031454 and K031337).

Description: The TGS v2.0 is a stereotaxic instrument that includes an optical detector, computer, dedicated instrumentation, operating software, tools and accessories, and a robotic arm. TGS v2.0 uses patient CT data to assist the physician with presurgical planning and interpretive/intraoperative navigation. The robotic arm serves as an "intelligent" tool holder or tool guide used by a surgeon for stereotactic guidance during minimally invasive orthopedic surgical procedures. The robotic arm, an electromechanical arm, is passively constrained by software-defined spatial boundaries implemented through the use of the 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 and awls.

Summary of Technological Characteristics:

The TGS v2.0 consists of the following basic components:

1. Robotic Arm
   - User Panel
   - Computer
   - CRISIS software application
   - QNX operating system
   - Power components
   - Uninterruptible Power Supply (UPS)
   - Cable panel
   - Positioning lever
   - Integrated cutting system
   - Isolation transformer
2. Guidance Module
   - High Resolution Color Liquid Crystal Display (LCD) Monitor
   - Computer
   - Software drivers for video grabber, standard computer components (keyboard, mouse, monitor, etc.)
   - Knee software application
   - Linux operating system
   - Keyboard and Mouse
3. Camera Stand
   - Second High Resolution LCD screen that shows an identical image to the primary touch screen

MAKO
SURGICAL CORP

2555 davie road fort lauderdale, florida 33317 tel 954.927.2044 fax 954.927.0446

- Optical Detector

4. Tool and accessories
   - Optically tracked surgical tools and accessories such as probes and arrays
   - Non-tracked tools and accessories such as drill guides, drill adapters, and screw drivers
5. Preoperative planning laptop
   - Runs only the preoperative planning portion of the application (up to the first implant planning step). 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 System

Intended Use/Indications for Use: The Tactile Guidance System v2.0 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 v2.0 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 and/or patellofemoral knee replacement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mako Surgical Corporation
% Mr. William F. Tapia
VP, Regulatory
2555 Davie Road
Davie, Florida 33317

NOV 2 5 2008

Re: K081867
Trade/Device Name: Tactile Guidance System v2.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: November 18, 2008
Received: November 20, 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.

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

MAKO
SURGICAL CORP.

2555 davie road fort lauderdale, florida 33317 tel 954.927.2044 fax 954.927.0446

EXHIBIT K

INDICATIONS FOR USE

510(k) Number (if known): K081867

Device Name: Tactile Guidance System v2.0

Indications for Use:

The Tactile Guidance System v2.0 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 v2.0 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 and/or patellofemoral 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 K081867