K050973

MAY 17 2005

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MAKO SURGICAL CORP.

2901 simms street hollywood, florida 33020 tel 954.927.2044 fax 954.927.0446

ATTACHMENT 17 - 510(K) SUMMARY

Submitter:	MAKO Surgical Corp.
Address:	2901 Simms Street, Hollywood, FL, 33020
Phone number:	954-927-2044
Fax number:	954-927-0446
Contact Person:	William F. Tapia
Date Prepared:	April 15, 2005
Cleared Device Trade Name:	Voyager Linux
Modified Device Trade Name:	Voyager Linux with the Tactile Guidance System (TGS)
Common Name:	Stereotaxic Instrument
Classification Name:	Class II
Classification #:	21 CFR 882.4560

Substantial Equivalence Claimed To: Voyager Linux; Z-KAT, Inc., K023975
The modification to the Voyager Linux to include the TGS is shown to be substantially equivalent to the cleared system in the previous 510k. As required by risk analysis, all verification and validation activities performed to date by designated individuals and the results demonstrated substantial equivalence.

Description: The Voyager Linux is an image guided surgical device that includes an optical detector, computer, dedicated instrumentation, operating software, tools and accessories, and the TGS. Voyager Linux uses patient data to assist the physician with presurgical planning and interpretive/intraoperative navigation. The TGS, which is an add-on to the Voyager Linux, serves as an "intelligent" tool holder or tool guide used by a surgeon for stereotactic guidance during minimally invasive orthopedic surgical procedures. The TGS, an electromechanical arm, is passively constrained by software-defined spatial boundaries implemented through the use of the TGS 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 3rd party drill systems.

Summary of Technological Characteristics - The Voyager Linux consists of the following basic components:

- High Resolution color liquid crystal display (LCD) touch screen monitor
- Uninterruptible Power Supply (UPS)
- Central Processing Unit (CPU)
- Isolation Transformer
- Keyboard and Mouse
- Optical Detector
- Operating Room Cart
- Tool and accessories – surgical tools and accessories instrumented with reflective markers.
- TGS – connected to the Voyager Linux platform to enable stereotactic guidance of standard surgical tools.
- Software – application specific software provided as part of system or via standard media (e.g., CD-ROM)

Intended Use: The Voyager Linux is intended for use as a device which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures.
The Voyager Linux is indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made, such as:

- Intra-cranial surgical procedures involving space occupying lesions or malformations (including soft tissue, vascular and osseous)
- Spinal surgical procedures involving spinal stabilization, neural decompression, or resection of spinal neoplasms

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2555 davie road, suite 10 fort lauderdale, florida 33317 tel 954.927.2044 fax 954.927.2046

- ENT Procedures
- Orthopedic surgical procedure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2005

Mr. William F. Tapia
Director of Regulatory Affairs
MAKO Surgical Corporation
2901 Simms Street
Hollywood, Florida 33020

Re: K050973
Trade/Device Name: Voyager Linux
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: April 29, 2005
Received: May 4, 2005

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 Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MAKO SURGICAL CORP.

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ATTACHMENT 15

INDICATIONS FOR USE

510(k) Number (if known): K050973

Device Name: Voyager Linux

Indications for Use:
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The Voyager Linux is indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made, such as:

- Intra-cranial surgical procedures involving space occupying lesions or malformations (including soft tissue, vascular and osseous)
- Spinal surgical procedures involving spinal stabilization, neural decompression, or resection of spinal neoplasms
- ENT Procedures
- Orthopedic surgical procedures

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)

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...diological Devices
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