

z-kat, inc.

DEC 20 2002

K023975

2901 simms street hollywood, florida 33020 tel 954.927.2044 fax 954.927.0446 zkat@z-kat.com www.z-kat.com

510(K) SUMMARY

SUBMITTER: Z-KAT, Inc.

ADDRESS: 2901 Simms Street

Hollywood, FL 33020

PHONE NUMBER: 954-927-2044

FAX NUMBER: 954-927-0446

CONTACT PERSON: Christina Vance

DATE PREPARED: November 27, 2002

TRADE NAME: Voyager Linux

COMMON NAME: Stereotaxic Instrument

CLASSIFICATION NAME: Class II

SUBSTANTIAL EQUIVALENCE CLAIMED TO:

1. Voyager 6.0 Software Option; Marconi Medical Systems, K000310

DEVICE DESCRIPTION:

The Voyager System is an image guided surgical device that includes an optical detector (infrared sensor), computer, dedicated instrumentation, and operating software. Voyager uses diagnostic images of the patient to assist the physician with presurgical planning and interpretive/interoperative navigation. Diagnostic image datasets describing internal and external patient anatomy or time sequences may be combined (superimposed) for comparison or to facilitate navigation during surgery.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

Voyager will consist of following basic components:

- 1) High Resolution color liquid crystal display (LCD) Touch Screen Monitor
- 2) Breakout Box
- 3) Tool Interface Unit (TIU)
- 4) Uninterruptable Power Supply (UPS)
- 5) Central Processing Unit (CPU)

- 6) Isolation Transformer
- 7) Keyboard and Mouse
- 8) Optical Detector (on wheeled-base pedestal)
- 9) Operating Room Cart
- 10) Tools and accessories – surgical tools and accessories instrumented with LEDs or reflective markers

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INTENDED USE:

The Voyager 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 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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 2002

Ms. Christina Vance
Regulatory Affairs Representative
Z-Kat, Inc.
2901 Simms Street
Hollywood, Florida 33020

Re: K023975
Trade/Device Name: Voyager Linux
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: November 27, 2002
Received: December 2, 2002

Dear Ms. Vance:

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.

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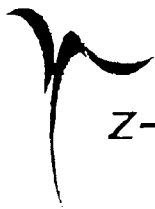
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



z-kat, inc.

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INDICATIONS FOR USE

510(k) Number (if known): K 023975

Device Name: Voyager

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over-the-Counter Use

(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K 023975