z-kat, inc.

APR 2 4 2003

K030764

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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: March 10, 2003

TRADE NAME: Z-Box

COMMON NAME: Stereotaxic Instrument

CLASSIFICATION NAME: Class II

CLASSIFICATION #: 21CFR 882.4560

SUBSTANTIAL EQUIVALENCE CLAIMED TO:

1. Voyager Linux; Z-KAT, Inc., K023975

DESCRIPTION:

The Z-Box System is an image guided surgical device that includes an optical detector (infrared sensor), computer, dedicated instrumentation, and operating software. Z-Box 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:

Z-Box will consist of following basic components:

1) High Resolution color liquid crystal display (LCD) touch screen monitor

2) Uninterruptible Power Supply (UPS)

3) Central Processing Unit (CPU)

4) Isolation Transformer

5) Keyboard and Mouse

6) Optical Detector (on wheeled-base pedestal)

7) Operating Room Cart

8) Tool and accessories – surgical tools and accessories instrumented with LEDs or reflective markers

9) dMIS kit – surgical instrument kit containing IGS tools and accessories and dMIS key

10) dMIS key – electronic storage media containing disposable software application

INTENDED USE:

The Z-Box 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 Z-Box 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 procedure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K030764
Trade/Device Name: Z-Box
Regulation Number: 21 CFR 882.4560
Regulation Names: Stereotaxic instrument
Regulatory Class: II
Product Codes: HAW
Dated: April 11, 2003
Received: April 14, 2003

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.

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) you may obtain. 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

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Miriam C. Provost

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

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