JUN 2 3 1999

K984298

Z-KAT, INC.

11645 Biscayne Blvd. Suite 308 Miami, FL 33181-3139 Tel 305.895.9022 Fax 305.895.8286 zkat@z-kat.com www.z-kat.com

510(k) Summary

Submitter: Z-KAT, Inc.

Address: 11645 Biscayne Blvd. Suite 304
Miami, FL 33181

Phone number: (305) 895-9022

Fax number: (305) 895-9023

Contact person: Rony Abovitz

Date prepared: November 18, 1998

Trade name: ***Z-KAT Fluorotactic ™ Guidance System***

Common name: Stereotaxic Instrument

Classification name: Class II

Substantial equivalence claimed to:

1. StealthStation, Surgical Navigation Technologies, Inc., K954276
2. Radionics Operating Arm & OTS System/StereoPlan, K961844
3. Picker International Viewpoint System, K970604
4. Fischer Imaging AutoGuide (Part of Mammotest Mammography System), K861692

Description:

The Fluorotactic Guidance System Mk. I is an integrated system that enables a surgeon to more accurately position drill guides, screw drivers, needles, and other surgical instruments using two captured fluoroscopic images. An electromechanical arm is used to accurately position an end-effector over the desired surgical area, and two approximately orthogonal images are captured with a standard flouroscope. The two images are displayed on computer monitors and used to perform accurate intra-operative planning. The plan consists of specifying the instrument entry point, and sagittal and transverse orientations. The system will then calculate the necessary coordinates for the robot arm, which will position the drill guide over the surgical area.

Summary of technological characteristics:

The Fluorotactic Guidance System Mk. I system will consist of four components:

1) Robot arm
2) Registration/drill guide artifact
3) Fluoroscopic image intensifier system (C-arm)
4) Personal computer (PC) with a Data Translation image acquisition card and two monitors

The robot arm will hold a registration artifact which is transparent to X-rays over the patient in proximity to the desired surgical area. This artifact has eight steel balls embedded such that when the C-arm is used to capture images of the area, the balls will create fiducial shadows on the image. Two images will be required, an Anterior/Posterior (A/P) view and a Sagittal view.

The PC will receive the image data from the C-Arm and display it on two monitors. The surgeon will indicate the desired positioning of the drill by manipulating a virtual guidewire on the screens. The software will then use the fiducial location information to calculate the coordinates for the positioning of the drill guide, and the robot arm will move to the new orientation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 1999

Mr. Rony Abovitz
Vice President, Biomedical Research and Development
Z-KAT, Inc.
11645 Biscayne Boulevard, Suite 304
Miami, Florida 33181

Re: K984298
Trade Name: Z-KAT Fluorotactic™ Guidance System
Regulatory Class: II
Product Code: HAW
Dated: March 30, 1999
Received: March 31, 1999

Dear Mr. Abovitz:

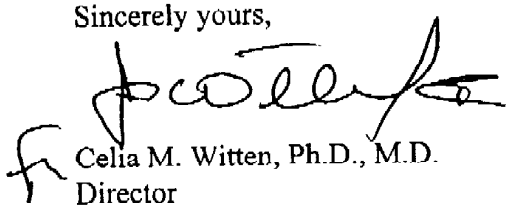
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

Enclosure

510(k) Number (if known): K984298

Device Name: ***Z-KAT Fluorotactic ™ Guidance System Mk. I***

Indications for Use:

The Fluorotactic Guidance System Mk. I will be used to assist in the accurate placement of a guiding device for surgery in which a linear trajectory insertion or placement is required. This system will use coordinated-fluoroscopy to allow intra-operative planning of the precise insertion point and angle of a device such as a screw, nail, or needle.

The surgeon will place a registration artifact over the desired surgical area and capture two fluoroscopic images, which will then be displayed on two computer screens. The surgeon will manipulate a virtual guidewire on the screens, until the desired angle and placement is achieved. The system will then output 3D coordinates to the robot arm which will move the drill guide to a precise position.

(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 Devices
510(k) Number K984298

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR 801.109)