K013025

OCT - 3 2001

z-kat, inc.

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510(K) SUMMARY

SUBMITTER: Z-KAT, Inc.

ADDRESS: 2903 Simms Street

Hollywood, FL 33020

PHONE NUMBER: 954-927-2044

FAX NUMBER: 954-927-0446

CONTACT PERSON: William F. Tapia

DATE PREPARED: August 23, 2001

TRADE NAME: FluoroLab Plus

COMMON NAME: Stereotaxic Instrument

CLASSIFICATION NAME: Class II

SUBSTANTIAL EQUIVALENCE CLAIMED TO:

1. The Fluorotactic Guidance System, Mk I, Z-KAT, Inc., K984298
2. StealthStation, Sofamor Danek, K954276
3. FluoroNav, Sofamor Danek, K990214
4. The Voyager; Marconi Medical Systems, K000310
5. VectorVision^2, BrainLab, K962939

DESCRIPTION:

FluoroLab Plus is an integrated system that helps a surgeon more accurately position drill guides, screw drivers, needles, and other surgical instruments using at least two captured fluoroscopic images. The acquired images are displayed on a flat panel monitor. Surgical tools and accessories are instrumented with LEDs or small reflective markers. Their positions and orientations are continuously tracked by an optical camera and updated in reference to the fluoroscopic images to provide constant navigational guidance to the target.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

FluoroLab Plus will consist of following basic components:

1) Registration phantom

2) Calibration grid

3) Fluoroscopic image intensifier system (C-arm)

4) Computer workstation with monitor and video acquisition box

5) Ergonomic cart

6) FluoroLab Plus software application

7) Optical camera with Tool Interface Unit (TIU)

8) Tools and accessories - surgical tools and accessories instrumented with LEDs or reflective markers

INTENDED USE:

FluoroLab Plus will be used for navigational guidance to position instruments during surgical procedures. It will provide a method of navigational guidance of tools through the use of a standard C-arm fluoroscope to capture images and an optical camera for instrument tracking. This increase in control will free the surgeon from the iterative process conventionally used, reduce the length of the surgical procedure, and enable minimally invasive procedure. In addition, since only two fluoroscopic images are needed, the exposure to X-rays is greatly reduced.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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William F. Tapia
Z-KAT, Inc.
2903 Simms Street
Hollywood, Florida 33020

Re: K013025
Trade/Device Name: FluoroLab Plus
Regulation Number: 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: II
Product Code: HAW
Dated: August 23, 2001
Received: September 10, 2001

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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,

Susan Weller, MD

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): K013025

Device Name: FluoroLab Plus

Indications for Use:

FluoroLab Plus will be used to assist in the alignment of surgical instruments by providing the surgeon with intraoperative navigational guidance based on pre-acquired fluoroscopic images. This system will use coordinated-fluoroscopy to allow intra-operative planning of the alignment of surgical tools such as a screw, nail, or needle.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use V OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

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

510(k) Number K013025