K05 1724

510 (K) SUMMARY

JUL 1 9 2005

SUBMITTER: EBI, L.P.

ADDRESS: 100 Interpace Parkway
Parsippany, NJ 07054

PHONE NUMBER: 973-299-9300

FAX NUMBER: 973-257-0232

CONTACT PERSON: Whitney Törning

DATE PREPARED: June 24 2005

TRADE NAME: The Acumen ™ Surgical Navigation System

COMMON NAME: Stereotaxic Instrument

CLASSIFICATION NAME: Stereotaxic Instrument

CLASSIFICATION #: Class II

SUBSTANTIAL EQUIVALENCE CLAIMED TO: Z-Box; Z-Kat, Inc. K030764

PURPOSE OF PREMARKET NOTIFICATION:

The Acumen™ Surgical Navigation System is identical to the previously FDA cleared Z-Kat Inc., Z-Box system which was cleared by FDA (K030764). EBI is submitting this 510(k) notice as a "duplicate 510(k)" due to a transfer of ownership of the technology.

DEVICE DESCRIPTION/SOFTWARE APPLICATIONS:

The Acumen ™ Surgical Navigation System has the same intended use and indications for use as stated in the Z-Box 510(k) notice except that EBI does not indicate use in intra-cranial surgical procedures involving space occupying lesions or malfunctions (including soft tissue,vascular and osseous) or for ENT procedures.

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The Acumen ™ Surgical Navigation System 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 Acumen ™ Surgical Navigation System 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:

- Spinal surgical procedures involving spinal stabilization, neural decompression, or resection of spinal neoplasms.
- Orthopedic surgical procedures

Technological Characteristics

The technical characteristics of the Acumen ™ Surgical Navigation System are the same as stated in the Z-Box 510(k) notice. The Acumen described in this notification consists of the same following components as the previously cleared Z-Box System by Z-Kat :

- High Resolution color liquid crystal display (LCD) touch screen
- Uninterruptible Power Supply (UPS)
- Central Processing Unit (CPU)
- Isolation Transformer
- Keyboard and Mouse
- Optical Detector (on wheeled-base pedestal)
- Operating Room Cart
- Tool and accessories – surgical tools and accessories instrumented with LED or reflective markers
- dMIS kit- surgical instrument lit containing IGS tools and accessories and dMIS key
- dMIS key- electronic storage media containing disposable software application

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Principles of Operation/Software Applications

The Acumen ™ Surgical Navigation System principles of operation are the same as stated in the Z-Box 510(k) notice (K030764).

The Acumen ™ Surgical Navigation System described in this notification consists of the same following software components as the previously cleared Z-Box System by Z-Kat :

- Software application
- Linux operating system
- Software drivers for video grabber, standard computer components (keyboard, mouse, monitor, etc.)

SUBSTANTIAL EQUIVALENCE

The Acumen ™ Surgical Navigation System is substantially equivalent to the Z-Box System by Z-Kat . The Acumen ™ Surgical Navigation System has the same intended use and indications, technological characteristics, and principles of operation and software applications as the previously cleared Z-Box System. The only difference is that EBI does not indicate use in intra-cranial surgical procedures involving space occupying lesions or malfunctions (including soft tissue, vascular and osseous) or for ENT procedures. This difference does not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2005

Ms. Whitney Törning
Manager of Regulatory Affairs
EBI, L.P.
100 Interpace Road
Parsippany, New Jersey 07054

Re: K051724
Trade/Device Name: Acumen™ Surgical Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: June 23, 2005
Received: June 27, 2005

Dear Ms. Törning:

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,

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

Indications for Use Statement

510(k) Number (if known): K051724

Device Name: Acumen ™ Surgical Navigation System

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- Orthopedic surgical procedures

Prescription Use ___X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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

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

510(k) Number K051724