APR 5 - 2007

K061479

APPENDIX 2

510(k) Summary of Safety and Effectiveness for ARGOS

Submitted By:

3D Line Medical System ,srl
Address: via Bernardo Rucellai 23 – 20161 MILAN – ITALY
Tel.: + 39 02 2550161
Fax: + 39 02 25501642

Contact Person: Marco Luzzara, Director, QA Manager

Summary Date: January 18,2006

Device Trade Name: ARGOS

Common Name: Image guided surgery system

Classification name: instrument, stereotaxic.

Predicate Device:

Vectorvision, (K003589)
manufactured by BRAINLAB AG
Ammerthalstrasse 8 Heimstetten, GM 85551

Description of the Device:

Argos is a system for computer-assisted stereotactic surgery. It is designed to be used as an aid to the location of, and surgical approach to, lesions within the anatomical structures on the human body and to help define the exact anatomical relations of such lesions to surrounding structures.
Prior to the brain surgery, the Argos system acquires contiguous MRI or CT scans of the area containing the lesion and uses them to construct an accurate three-dimensional representation of the patient's anatomy used initially to facilitate surgical planning.
During the operation the Argos system continuously monitors the position of a pointing instrument, used by the surgeon, and visualizes it on a monitor screen in relation to the three-dimensional virtual anatomy of the patient. It is therefore possible to verify during the operation that the real position of various anatomical reference points, including the lesion, corresponding to those identified during surgical planning.

Intended use of the device:

Argos is intended as an aid to the surgeon for precisely locating anatomical structures on the human body in either open or percutaneous procedures. It links tracked probes to virtual computer image space on a patient's preoperative or intraoperative image data. The system is indicated for any medical condition in which the use of stereotactic surgery may appropriate and where the reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra can be identified relative to medical images such as CT, MR , fluoroscopic or ultrasound images.

Example procedures include but are not limited to:

Cranial Procedures:
Cranial biopsies
Tumor resection
Craniotomies/Craniectomies
Skull base procedures
Thalamotomies/Pallidotomies

Spinal Procedures:
Spinal implant procedures such as pedicle screw placement

ENT procedures:
Transsphenoidal procedures
Intranasal procedures
Sinus procedures, such as Maximillary anstrostomies, Ethmoidectomies
Sphenoidotomies/Sphenoid explorations, Turbinate resection and Frontal sinusotomies

Substantial Equivalence to Predicate Device:

ARGOS and VECTORVISION are both image guided surgery systems. They link tracked probes to virtual computer image space on a patient's image. The relevant characteristics are compared below.

	ARGOS	VECTORVISON
Indication for Use	3Dline Argos is intended as an aid to the surgeon for precisely locating anatomical structures on the human body in either open or percutaneous procedures. It links tracked probes to virtual computer image space on a patient's preoperative or intraoperative image data. The system is indicated for any medical condition in which the use of stereotactic surgery may appropriate and where the reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra can be identified relative to medical images such as CT, MR, fluoroscopic or ultraosund images.	BRAINLAB VectorVision is intended to be an intraoperative image guided localizaton system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative image data being processed by a VectorVision workstation. The 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, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-ray or MR based model of anatomy.
Device main components	▪ Argos Controller, consisting of computers and touch-screen monitor. ▪ The Camera System, consisting of infrared cameras that can be stand alone (on wheels), mounted on the controller or mounted on the operating microscope. ▪ Localizers and Pointers ▪ Planning Workstation (optional), that allows the pre-operative planning	▪ Brainlab VectorVision navigation system integrates computers, touch-screen monitors and infrared cameras. The video cameras cannot be separated from the main unit. ▪ Workstation for pre-operative planning ▪ Localizers and pointers
Physical characteristics	Main Unit: Height 152cm Width 51 cm Depth 54 cm Weight ca. 80Kg Camera System (Type SS): Height 12 cm (30cm width the handle) Width 62cm Depth 16 Weight ca. 4.0kg Camera System (Type M): Height 4.6 cm Width 16cm Depth 9.5 Weight ca. 0.8 kg	Main Unit: Height 162cm Width 95cm (115cm max) Depth 72cm Weight ca.150Kg Camera System: Height 9.5 cm Width 62cm Depth 16.5 Weight 2.5kg

	ARGOS	VECTORVISON
Localization technology	Optical tracking, based on infrared cameras and wire-less passive instruments (by means of retro-reflective markers). The objects to be tracked are fitted with retro-reflective markers. The images coming from the video cameras are processed and the 3D coordinates of the markers are calculated by triangulation.	Optical tracking, based on infrared cameras and wire-less passive instruments (by means of retro-reflective markers). The objects to be tracked are fitted with retro-reflective markers. The images of the video cameras are processed and the 3D coordinates of the markers are calculated by triangulation.

Conclusion: ARGOS has been found to be substantially equivalent to BRAINLAB VECTORVISION, 510/k) No. K003589.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 - 2007

3D Line Medical Systems S.R.L.
% TUV America, Inc.
Mr. Stefan Preiss
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K061479
Trade/Device Name: ARGOS
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: March 19, 2007
Received: March 21, 2007

Dear Mr. Preiss:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K061479

Device Name: ARGOS

Indications for Use:

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Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 801 Subpart C)

(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, and Neurological Devices

510(k) Number K061479