K080678

510 (k) Summary of Safety and Effectiveness for BrainLAB uni-knee

JUN - 6 2008

Manufacturer:

Address:	BrainLAB AG Kapellenstrasse 12 85622 Feldkirchen Germany	
	Phone:	+49 89 99 15 68 0
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Contact Person:	Mr. Per Persson	

Summary Date: 16 January 2008

Device Name:

Trade name:	Uni-knee 2.0
Common/Classification Name:	BrainLAB uni-knee, BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Device:
Vector Vision® CT-free Knee (K021306)
Ci TKR/UKR (K052966)
VectorVision uni-knee (K041899)

Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II

Intended Use:

BrainLAB uni-knee is intended to be an intraoperative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on an individual 3D model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate 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 the anatomy. The system aids the surgeon in accurately navigating a knee endoprosthesis to the intraoperatively planned position. Ligament balancing and measurements of bone alignment are provided by **BrainLAB uni-knee.**

Example orthopedic surgical procedures include but are not limited to:
- Unicondylar Knee Replacement
- Ligament Balancing
- Range of Motion Analysis
- Patella Tracking

Device Description:
BrainLAB uni-knee is intended to enable 3 dimensional implant planning and navigation for unicompartimental orthopedic knee surgery. The SW links a surgical instrument tracked by passive markers to a 3D-model of the patient's bone, which is generated by acquiring multiple landmarks on the bone surface. Uni-knee 2.0 uses the registered landmarks to navigate the femoral and tibial cutting guides to the pre-planned position.

Uni-knee 2.0 allows 3-dimensional reconstruction of the mechanical axes and alignment of the implants. The uni-knee 2.0 software has been designed to read in implant data and tool data from different manufacturers and offers to individually choose the prosthesis during each surgery. The uni-knee 2.0 software registers the patient data needed for planning and navigating intra-operatively. No preoperative CT-scanning is necessary.

Substantial equivalence:
VectorVision® uni-knee has been verified and validated according to BrainLAB's procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with predicate devices such as the 510(k)-clearance of VectorVision® uni-knee (K041899), VectorVision® CT-free knee (K 021306) and Ci TKR/UKR (K052966).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2008

BrainLAB AG
% Mr. Per Persson
Kapellenstrenstrasse 12
85622 Feldkirchen
Germany

Re: K080678
Trade/Device Name: uni-knee
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: March 6, 2008
Received: March 10, 2008

Dear Mr. Persson:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

Indications for Use

510(k) Number (if known): K080678

Device Name: uni-knee

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- Patella Tracking

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

510(k) Number K080678

Prescription Use ____X____ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)