KO42513

510 (k) Summary of Safety and Effectiveness
for VectorVision® Osteotomy

Manufacturer:

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Contact Person: Mr. Rainer Birkenbach

Summary Date: 26th August 2004

Device Name:

Trade name: VectorVision® Osteotomy

Common/Classification Name: VectorVision, BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Device:
Vector Vision® ct free knee (K 021306)

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

Intended Use:
BrainLAB VectorVision 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 to assist a surgeon to perform one (open wedge) or two (closed wedge) cuts to achieve a leg angle correction.

Example orthopedic surgical procedures include but are not limited to:

Open wedge osteotomy for the lower limb
Closed wedge osteotomy for the lower limb

Device Description:

BrainLAB VectorVision®Osteotomy is intended to enable 3 dimensional correction planning and navigation for lower limb osteotomies. The SW links a surgical instrument tracked by passive markers to a model of the patient's bone geometry, which is generated by acquiring multiple landmarks on the bone surface. VectorVision® Osteotomy uses the registered landmarks to navigate the tibial cutting guides to the pre-planned position. Leg geometry correction can be tracked continuously until osteosynthesis.

High Tibial Osteotomy is like total and unicondylar knee arthroplasty a common therapy for osteoarthritis. Actually it obtains its relevance back because it seems more sensible to preserve normal articular cartridge as long as possible instead of early joint replacement.

Two different kinds of operational procedure are in use. Open wedge osteotomy and closed wedge osteotomy. Open wedge osteotomy: One cut is performed on a planned level of the tibia and when spreading this cut open the leg geometry is changed. For the treatment of more common medial gonarthrosis the open wedge option is performed on the medial side of the tibia. The opened cut is fixed with a special plate designed for this treatment.

The open wedge technique provides an easier surgical approach, less vulnerable structures can interfere. But with great correction angles (>10°) the opened bone wedge gets unstable.

Closed wedge osteotomy: Two cuts with a certain angulation are peformed on the tibia. When the wedge, resulting from these two cuts, is removed a gap occurs which is closed by bringing both cutting planes together. The fixation of this situation is less difficult as the situation bone on bone provides certain stability. The medial gonarthrosis is treated from the lateral side.

For greater correction angels the lateral closing wedge technique gives more stability. But the approach is more difficult and in most of the cases the fibular bone must be cut too.

The whole procedure can be performed without any additional imaging technique.

Substantial equivalence:

VectorVision® Osteotomy has been verified and validated according to BrainLAB's procedures for product desig and development. The validation proves the safety and effectiveness of the system. The information provided b' BrainLAB in this 510 (k) application was found to be substantially equivalent with the 510(k)-clearance of VectorVision® CT-free knee (K 021306).

The VectorVision® CT-free knee software calculates all planning values based on the same registered landmark and parameters equally to the VectorVision® osteotomy software. The initial geometry of the leg is digitized the same way. For the knee software the registered leg geometry is used to calculate position and size of the used implants. In the osteotomy software the leg geometry itself is used to create the plan of treatment, as the geometry correction is the task. In summary it can be stated the both applications use the same calculation, th output of the VectorVision® CT-free knee software contains several continuative steps until planring result is completed.

FEB 1 0 2005

Mr. Rainer Birkenbach
Executive Vice President
BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany

Re: K042513
    Trade/Device Name: VectorVision Osteotomy
    Regulation Number: 21 CFR 882.4560
    Regulation Name: Stereotaxic instrument
    Regulatory Class: II
    Product Code: HAW
    Dated: January 19, 2005
    Received: January 24, 2005

Dear Mr. Birkenbach:

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.
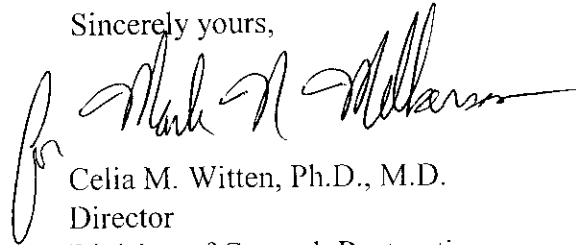
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,

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

510(k) Number (if known): _____K042513_____

Device Name: _____VectorVision Osteotomy_____

Indications For Use:

BrainLAB VectorVision 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.
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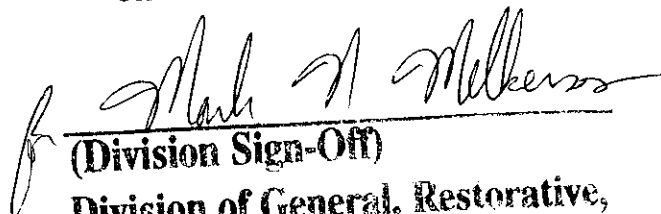Closed wedge osteotomy for the lower limb

Prescription Use ___X___   AND/OR   Over-The-Counter Use ·_____
(Per 21 CFR 801 Subpart D)   (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_____K042513_____