K102990

APR - 4 2011

510 (k) Summary of Safety and Effectiveness for *Brainlab knee*

Manufacturer:

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85622 Feldkirchen
Germany
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Contact Person: Mr. Alexander Schwiersch

Summary Date:

Device:

Trade name:	*Brainlab knee*
Common/Classification Name:	*Brainlab knee*, BrainLAB Image Guided Surgery System / Instrument, Stereotaxic
Regulation Number:	21 CFR 852.4560
Product code:	OLO

Predicate Device:
Brainlab knee (K073615)
PiGalileo Total Knee Replacement (TKR) System (K061362)

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

Intended Use:

Brainlab 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, MR-based model of the anatomy. The system aids the surgeon to accurately navigate a knee prosthesis to the intraoperatively planned position. Ligament balancing and measurements of bone alignment are provided by ***Brainlab knee***.

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

Device Description:

Brainlab knee is an image guided surgery system for total knee replacement surgery based on landmark based visualization of the femur and tibia.

Substantial equivalence:
Brainlab knee has been verified and validated according to BrainLAB procedures for product design and development. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate device *Brainlab knee* (K073615) and "PiGalileo Total Knee Replacement (TKR) System (K061362)".

Changes to Predicate Device
Brainlab knee has changed in the following from *Predicate Device:*

- Compatibility to Smith&Nephew's Motorized Cutting Guide (MCG). Which itself has FDA clearance under *PiGalileo* Total Knee Replacement (K061362). The *MCG* is brings the cutting block into the position, which is planned in the software.

- Alignment Verification Procedure. A condensed workflow, based entirely on existing algorithms without the necessity to attach reference arrays to the bone. This procedure allows measurement of the alignment of a static cutting block with patient anatomy.

- Disposable Clip-on Remote Control. A facultative enhancement of the existing pointer. Instead of pivoting the user can press a button on the clip to acquire points. It is also possible to acquire direction with a simple button click instead of holding the pointer still.

Verification/validation summary
To verify the correct functionality of the system *Brainlab knee*, all relevant test documentation coming from the risk analysis and specifications of each component has been compiled into one system. The system guarantees that all risks and associated tests are traceable and verify that no open risks or untested specifications occur. All inherited modules such as hardware platform, instruments, licenses etc. are taken into account.
The functionality is verified on all released platforms. BrainLAB industrial designers verified compliance of the interface to Brainlab standard. Workbench test have been

performed on precisely milled model bones. Cut and implant positions have been compared to theoretical values.

The following validation methods were used to validate system *Brainlab Knee*:

- Comparison of the design to a previous product having an established history of successful use
- Literature research and corresponding database search
- Testing and evaluation under real world conditions
- Usability tests, prototyping and simulations
- Design reviews
- Software Validation

Validation activities have successfully been performed according to the indications for use. The validation is supported by design reviews with many of the initial design surgeons and a cadaver test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

BrainLAB AG
% Mr. Alexander Schwiersch
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85622 Feldkirchen, Germany

APR - 4 2011

Re: K102990
Trade/Device Name: Brainlab Knee
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 24, 2011
Received: March 28, 2011

Dear Mr. Schwiersch:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102990

Device Name: Brainlab Knee

Indications For Use:

Brainlab 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, MR-based model of the anatomy. The system aids the surgeon to accurately navigate a knee prosthesis to the intraoperatively planned position. Ligament balancing and measurements of bone alignment are provided by **Brainlab Knee**.

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- Total Knee Replacement
- Ligament Balancing
- Range of Motion Analysis
- Patella Tracking

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)

Neil R Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102990