June 3, 2022

Brainlab AG
Chiara Cunico
Manager Regulatory Affairs
Olof-Palme-Str. 9
Munich, Bavaria 81829
Germany

Re: K220652
Trade/Device Name: Knee 3
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 1, 2022
Received: March 7, 2022

Dear Chiara Cunico:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220652

Device Name
Knee 3

Indications for Use *(Describe)*
Knee3 is intended to be an intraoperative localization system used during orthopedic knee surgery. It links a navigated instrument, tracked by a passive marker sensor system, to virtual computer image space on an individually acquired model of the patient's anatomical axes, which are generated through acquiring multiple anatomical bony landmarks. The system is indicated for medical conditions in which the use of stereotaxic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the femur and tibia, can be identified relative to the acquired anatomical landmarks. The system aids the surgeon to plan resections, measure cutting block alignment, measure bone resections, and/or leg alignment. The device is indicated for total and uni-compartmental knee replacement.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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BRAINLAB

510(k) Summary

May 25, 2022

General Information	
Manufacturer	Brainlab AG; Olof-Palme Str.9, 81829, Munich, Germany
Establishment Registration	8043933
Device Name	Orthopedic Stereotaxic Instrument
Trade Name	Knee 3
Classification Name	Stereotaxic instrument
Product Code	OLO
Regulation Number	882.4560
Regulatory Class	II
Panel	Orthopedic
Predicate Devices	Primary predicate device: Brainlab Knee (Knee 2.5) K102990 Secondary predicate device: uni-Knee (Uni-Knee 2.0) K080678 Tertiary predicate device: DASH Knee (DASH Knee 1.0) (K102251)

Contact Information	
Primary Contact	**Alternate Contact**
Chiara Cunico Manager RA Phone: +49 89 99 15 68 0 Email: chiara.cunico@brainlab.com	Regulatory Affairs Brainlab Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 5033 Email: regulatory.affairs@brainlab.com

1. Indications for Use

Knee3 is intended to be an intraoperative localization system used during orthopedic knee surgery. It links a navigated instrument, tracked by a passive marker sensor system, to virtual computer image space on an individually acquired model of the patient's anatomical axes, which are generated through acquiring multiple anatomical bony landmarks. The system is indicated for medical conditions in which the use of stereotaxic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the femur and tibia, can be identified relative to the acquired anatomical landmarks. The system aids the surgeon to plan resections, measure cutting block alignment, measure bone resections, and/or leg alignment.
The device is indicated for total and uni-compartmental knee replacement.

2. Device Description

The Knee3 is a software application module intended to be used on compatible navigation platforms that assist in the implantation of prosthetic knee implants. It uses instruments and accessories such as reference arrays, pointers and plane tools, which are tracked by an infrared camera of the respective platform, to determine femur and tibia anatomical landmarks as well as instrument positions in relation to the registered bones. The resulting navigation measurements support the user with the placement of the cutting guides.

Tracking Principle	Infrared passive and active marker based tracking as provided by the optical tracking camera unit of the navigation station.
Navigation	The relation between the patient and the reference attached to the patient is realized with a manual registration using instruments. The Knee3 software receives position and orientation of tracked instrument accessories and calculates the navigation measurements out of their relations to each other. The measurement values are displayed within the software graphical user interface on the respective platform screen.
Display	LCD display with capacitive dual touch technology.

3. Substantial Equivalence

Devices	Name (version)	K-Number	Manufacturer
Subject Device	Knee3 (Knee 3.3)	N/A	Brainlab AG
Primary Predicate	Brainlab Knee (Knee 2.5)	K102990	Brainlab AG
Secondary Predicate	uni-Knee (Uni-Knee 2.0)	K080678	Brainlab AG
Tertiary predicate	DASH Knee (DASH Knee 1.0)	K102251	Brainlab AG

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Infrared optical tracking is the technological principle for both the subject and predicate devices. It is based on the use of instruments with reflective marker technology.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Same localization and referencing techniques
- Same user interface technology
- Same remote control devices
- Same general acquisition methods
- Mostly the same registration steps that make up the bone coordinate systems
- Instruments are made of surgical grade materials
- Instruments are pre-calibrated

The following technological differences exist between the subject and predicate devices:

- User interface visual design
- Software user guidance

- Some landmark registrations
- Compatible platform devices and accessories

However, these differences do not raise any new questions of safety or efficacy because the performance of the subject device has thoroughly been verified for its efficacy.

4. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

System

The technical navigation accuracy (bench accuracy) of the overall system consisting of platform, software and instruments has been evaluated on a bench model and has shown to be within limits of ± 2° for angles and ± 2mm for distances in 95% of cases.

Instruments

The safety and effectiveness of the Knee3 Instruments has been verified. Technical performance has been tested on the following main aspects:

- **Instrument system integration testing**: the Knee3 instruments have been proven to meet the accuracy requirements for use with Knee3.
- **Mechanical stability testing**: the mechanical stability of the Knee3 instruments has proven to be sufficient for the intended use.
- **Biocompatibility**: the Knee3 instruments with intended patient contact have been supported as biocompatible.

Biocompatibility testing

The biocompatibility evaluation for the Knee3 surgical instruments was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity tests acc. to ISO 10993-5
- Chemical analysis acc. to 10993-12 and 10993-18 for quantification and characterization of organic leachables and extractables

In addition, the following biological endpoints were evaluated based on the test results:

- Sensitization acc. to ISO 10993-10
- Irritation acc. to ISO 10993-10
- Materials-Mediated Pyrogenicity acc. to ISO 10993-11

- Acute Systemic Toxicity acc. to ISO 10993-11

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since failures or latent flaws could prior to mitigation of hazards result in serious injury to the patient. Information provided by the software drives a decision through the user, that, if misapplied, could result in serious injury.

Clinical Validation:
Clinical Validation for the Subject Device was carried out to establish equivalence of the subject device workflows (Motion, Universal, Partial and Express) to the workflows contained within the identified predicate devices.
Clinical data gathered from literature was used to validate the accuracy of the predecessor software device versions (predicate devices) and respective workflows.

5. Conclusion

The comparison of the Knee3 with the predicate device(s) Brainlab Knee, Uni Knee and DASH Knee shows that the Knee3 has similar functionality, intended use, technological characteristics, and typical users as the predicate devices. Verification and validation activities ensured that the design specifications are met and that the Knee3 does not introduce new issues concerning safety and effectiveness. Hence, the Subject Device is substantially equivalent to the predicate device.