June 2, 2020

Brainlab AG
℅ Cherita James
Regulatory Consultant
M Squared Associates Inc.
575 8th Ave
Suite 1212
New York, New York 10018

Re: K193307
Trade/Device Name: Hip7
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 1, 2020
Received: April 2, 2020

Dear Cherita James:

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, MPH
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193307

Device Name
HIP7

Indications for Use *(Describe)*
HIP7 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 either on a patient's preoperative image data being processed by Brainlab IGS platforms, or 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 considered to be safe and effective, and where a reference to a rigid anatomical structure, such as 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 to accurately navigate a hip endoprosthesis to the preoperatively or intraoperatively planned position.
Example orthopedic surgical procedures for the Computer Assisted Total Hip Replacement – HIP7 use case include but are not limited to:

- Total Joint Replacement
- Minimally invasive orthopedic surgery

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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K193307

510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for Brainlab's HIP7 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

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Date of Submission: March 26, 2020

Proprietary Name: HIP7

Common Name: Stereotaxic Instrument

Regulatory Class: Class II

Regulation: 21 CFR 882.4560

Product Codes: OLO

Predicate Device(s): K122011 Brainlab Hip

Device Description: The HIP7 system is intended to enable navigation in orthopedic hip replacement surgery. It links a surgical instrument, tracked by flexible passive markers to virtual computer image space on an individual three-dimensional model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface or soft tissue. The HIP7 system uses the registered landmarks to navigate the necessary surgical tool, i.e., cup inserter, to the desired orientation. Additionally, it enables to intra-operatively measure the changes in leg length and offset.

The HIP7 system provides a three-dimensional reconstruction of the relevant anatomical axes and planes of the femur and pelvis to aid the alignment of the implants and to determine leg length and offset parameters. Based on the selected procedure, the HIP7 system loads implant and instrument data that has been provided by the implant manufacturer. The implant is selected according to the available license and is then shown in the software in relation to the determined anatomical structures. A preoperative x-ray may optionally me loaded. The HIP7 system does not require CT-based imaging.

Indications for Use: HIP7 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 either on a patient's preoperative image data being processed by Brainlab IGS platforms, or 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 considered to be safe and effective, and where a reference to a rigid anatomical structure, such as 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 to accurately navigate a hip endoprosthesis to the preoperatively or intraoperatively planned position.

Example orthopedic surgical procedures include but are not limited to:

- Total Joint Replacement
- Minimally invasive orthopedic surgery

SE Table

Features/Technical Information	Predicate device **Brainlab hip (Hip 6.0)**	New device **HIP7**	Substantial Equivalence
510(k) number	K122011	-	-
Indication for Use	Total Hip Replacement (THR) procedures The Brainlab Hip system 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 either on a patient's preoperative image data being processed by Brainlab IGS platforms, or on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. The	HIP7 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 either on a patient's preoperative image data being processed by Brainlab IGS platforms, or 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	Same indication for use with limited intended uses. Difference does not present new issues of safety and effectiveness.

Features/Technical Information	Predicate device **Brainlab hip (Hip 6.0)**	New device **HIP7**	Substantial Equivalence
	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 the anatomy. The system aids the surgeon to accurately navigate a hip endoprosthesis to the preoperatively or intraoperatively planned position. Example orthopedic surgical procedures include but are not limited to: • Total Joint Replacement • Minimally invasive orthopedic surgery • Tumor resection and bone/joint reconstruction Surface Replacement (SR) procedures	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 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 to accurately navigate a hip endoprosthesis to the preoperatively or intraoperatively planned position. Example orthopedic surgical procedures include but are not limited to: • Total Joint Replacement • Minimally invasive orthopedic surgery	
Intended Use	intraoperative image-guided localization system to enable	intraoperative image-guided localization system to enable	Tumor resection and bone/joint reconstruction and Surface replacement

Features/Technical Information	Predicate device **Brainlab hip (Hip 6.0)**	New device **HIP7**	Substantial Equivalence
	minimally invasive surgery including: • Total Joint Replacement • Minimally invasive orthopedic surgery • Tumor resection and bone/joint reconstruction • Surface Replacement procedures	minimally invasive surgery including: • Total Joint Replacement • Minimally invasive orthopedic surgery Tumor resection and bone/joint reconstruction and Surface replacement procedures have been excluded.	procedures have been excluded. Difference does not present new issues of safety and effectiveness.
Pelvis Registration	There is a pelvis registration for supine and one for lateral patient position. The ASIS-ASIS distance is measured pre-operatively with the caliper.	The registration procedures have been modified: - measurement of ASIS-ASIS distance manually (with caliper) or digitally (on pre-operative X-ray) - elimination of the acquisition of one landmark (anterior rim point is now constructed from the calculated acetabular sphere)	Confirmed in verification of device/system performance. Difference does not present new issues of safety and effectiveness.
Plausibility checks	Contains plausibility checks	Plausibility checks were removed (due to eliminated features),	Difference does not present new issues of safety and effectiveness.

Features/Technical Information	Predicate device **Brainlab hip (Hip 6.0)**	New device **HIP7**	Substantial Equivalence
		adjusted (tighter rules) and added.	
Cup Navigation	Cup orientation values (inclination, anteversion) are displayed in combination with a visualization of a pelvis model and the navigated implant. When pelvic tilt was entered via a control, the inclination and anteversion values to both the anterior pelvic plane (APP) and functional plane are shown next to each other in the controls. The pelvic tilt value is shown on the screen.	Cup orientation values (inclination, anteversion) are displayed in combination with a visualization of a pelvis model, the navigated implant and the reference planes. When a pelvic tilt (PT) value is available, the inclination and anteversion values to both the anterior pelvic plane (APP) and functional plane are displayed in individual controls. PT can be entered manually via control or calculated automatically if appropriate pre-operative planning data is available (X-ray planned with specific TraumaCad measurement tool). The PT value is shown on the screen.	In addition to the manual entry of the pelvic tilt, the value can now also be calculated automatically if TraumaCad planning data is available. Acceptance criteria for measuring inclination and anteversion had been defined for Hip 6.0. Verification tests have shown that these acceptance criteria are also met when inclination and anteversion are measured in relation to a functional plane (including automatic calculation of pelvic tilt). Difference does not present new issues of safety and effectiveness.
Leg Length & Offset Measurement	The global leg length and offset change (combined change resulting from implanted cup and stem) can be measured intraoperatively with trial and final implants. There are two options: with a reference array attached to the femur with pins or with a	The global leg length and offset change can be measured intraoperatively with trial and final implants. There is only one option: with a reference array attached to the lower thigh with adhesive foil.	The functionality of the remaining measurement procedure is unchanged. Difference does not present new issues of safety and effectiveness.

Features/Technical Information	Predicate device **Brainlab hip (Hip 6.0)**	New device **HIP7**	Substantial Equivalence
	reference array attached to the lower thigh with adhesive foil.		
Compatible platforms	- Kolibri Navigation Station 2.0 (Windows XP SP 3) - VectorVision Compact (Workstation 6 with Windows XP SP 3) - VectorVision² (Workstation 6 with Windows XP SP 3) - VectorVision Sky (Workstation 6 with Windows XP SP 3) - VectorVision Flex (Workstation 6 with Windows XP SP 3) - **Curve (Windows 7 (64 Bit))** - **Kick (Windows 7 (64 Bit))*** - **Kick 2 (with Spectra camera only) (Windows 8.1 (64 Bit))*** - **Curve Ceiling-Mounted**	- Kick (Windows 7 (64 Bit))* - Kick 2 (with Spectra and Vega camera) (Windows 8.1 (64 Bit))* - Curve (Windows 7 (64 Bit))* - Curve Ceiling-Mounted (Windows 7 (64 Bit)) ** - Curve 1.2 Dual Navigation Station (Windows 8.1 (64 Bit))* - Curve 1.2.1 Dual Navigation Station (Windows 10 (64 Bit))* - BUZZ Navigation (Ceiling-Mounted) (Windows 10 (64 Bit))* *All platforms marked with * received FDA clearance with K183605*	Difference does not present new issues of safety and effectiveness

Features/Technical Information	Predicate device **Brainlab hip (Hip 6.0)**	New device **HIP7**	Substantial Equivalence
	(Windows 7 (64 Bit))* - **Curve 1.2 Dual Navigation Station (Windows 8.1 (64 Bit))*** * *letter to file*	*Spine & Trauma Navigation.* *The platform marked with ** received FDA clearance with K092467 Cranial Navigation.*	
Compatible instruments	Contains a large number of compatible instruments for all available workflow steps. See Hip and Knee Instrument User Guide of original submission	The list of compatible instruments has been reduced in accordance with the features removed. The Bone Fixator 2-Pin Flip Flop was added to the list of compatible instruments *(received FDA clearance with K183605 Spine & Trauma Navigation System)* The following instruments / accessories have been added: Cup Impactor Universal Straight, Pin Driver Adapter for AO Coupling, KingMark Calibration Device See Section 8 Device Description and Appendix 11-1, 11-2 Instrument User Guide Hip	New instruments/accessories have been verified to perform as intended. Difference does not present new issues of safety and effectiveness

Similarities:

- same type of platform (computer, touchscreen, tracking camera)
- same tracking technology (infrared tracking with passive marker spheres)
- most instruments are the same (available selection was reduced, four instruments / accessories added)
- workflows (available selection was only reduced)
- registration procedure and landmarks to be registered (required number of landmarks was only reduced)
- navigated values (inclination, anteversion; leg length (longer/shorter), offset (medial/lateral))
- content of GUI (displayed pictures)

Differences:

- new GUI design
- optional use of data from pre-operatively planned X-ray for calculation of ASIS-ASIS distance
- optional use of data from pre-operatively planned X-ray for calculation of pelvic tilt
- compatibility to old platforms removed and compatibility to new platforms added (All compatible platforms have already received FDA clearance with the predicate device K122011, or with K183605 or K092467.)
- added Bone Fixator 2-Pin Flip Flop to list of compatible instruments (received FDA clearance with K183605 Spine & Trauma Navigation System)
- three new instruments / accessories

Technological Characteristics and Substantial Equivalence

The HIP7 system has been verified and validated according to Brainlab's procedures for product design and development.

Summary

The changes described above do not alter intended use or the fundamental scientific technology of the device because they do not change the operating principle. The changes to the HIP7 do not present any new issues of safety and effectiveness when compared to the predicate device.

The HIP7 system described in this submission is, in our opinion, substantially equivalent to the predicate.