December 23, 2020

Brainlab AG
Cunico Chiara
Manager Regulatory Affairs
Olof-Palme-Str. 9
Munich, 80809
Germany

Re: K202320
Trade/Device Name: CIRQ Robotic Alignment Module, Cirq, Cirq Robotic Alignment Module Spinal, Cirq Robotic Alignment Cranial and Spine, CIRQ Robotic Alignment Cranial and Spine System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 17, 2020
Received: November 19, 2020

Dear Cunico Chiara:

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)*
K202320

Device Name
CIRQ Robotic Alignment Module, Cirq, Cirq Robotic Alignment Module Spinal, Cirq Robotic Alignment Cranial and Spine, CIRQ Robotic Alignment Cranial and Spine System

Indications for Use *(Describe)*
For spinal use the CIRQ Robotic Alignment Module is an accessory to the compatible Brainlab IGS Spinal software applications and is intended to be an intraoperative image guided localization system to support the surgeon to achieve pre-planned trajectories with surgical instruments.

The medical indications for use of the CIRQ Robotic Alignment Module for spinal use is the treatment of diseases where the placement of spinal screws is indicated.

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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510(k) Summary

November 17, 2020

General Information	
Manufacturer	Brainlab AG
Establishment Registration	8043933
Device Name	CIRQ Robotic Alignment
Trade Name	Cirq, Cirq Robotic Alignment System, Cirq Robotic Alignment Module Spinal, Cirq Robotic Alignment Cranial And Spine, CIRQ Robotic Alignment Cranial and Spine System
Classification Name	Orthopedic Stereotaxic Instrument
Product Code	OLO
Regulation Number	882.4560
Regulatory Class	II
Panel	Orthopedic
Predicate Device and K Number	Spine Trauma 3D – K183605

Contact Information	
Primary Contact	**Alternate Contact**
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1. Intended Use and Indication for Use

For spinal use the CIRQ Robotic Alignment Module is an accessory to the compatible Brainlab IGS Spinal software applications and is intended to be an intraoperative image guided localization system to support the surgeon to achieve pre-planned trajectories with surgical instruments.

The medical indications for use of the CIRQ Robotic Alignment Module for spinal use is the treatment of diseases where the placement of spinal screws is indicated.

2. Device Description

The device is an accessory to the compatible Brainlab IGS Spinal software applications (K183605) and is intended to be an intraoperative image guided localization system to support the surgeon to achieve pre-planned trajectories with surgical instruments.

The device consists of the Cirq Robotic Alignment Module which is connected to the Surgical Base System from Medineering. It serves to align instruments to a pre-planned trajectory during surgical

procedures using the Cirq Robotic Application Software together with the Brainlab IGS Spinal software applications.

Infrared passive marker based tracking as provided by the optical tracking camera unit of the navigation platform is used to determine the instrument's and patient's position. The relation between the patient and the reference attached to the patient is realized with a registration (manually or automatically).

The device is manually pre-aligned roughly to the region of interest by opening the brakes of the Surgical Base System using its 7 degrees of freedom. Following this, the tracking information is used to automatically fine align a tracked guide attached to the Cirq Robotic Alignment Module to achieve a pre-planned trajectory controlled by the CIRQ Robotic Application Software. After finishing the alignment, the device remains in this position and the surgeon can use surgical instruments through the provided guide to perform the surgical steps intended without losing the trajectory.

3. Substantial Equivalence

The subject device has been compared with the predicate device (K183605). The main differences are listed below. Please see Substantial Equivalence Cirq Robotic Alignment Module for full details as well as the demonstration of equivalence.

Topic	Changes included in Subject Device Cirq Robotic Alignment Module
Platform	• Updated IGS platform with Touchscreen Monitor and Stereotactic Camera system
Instruments / Hardware Components	• Surgical Base System communicates with Navigation platform and attached Cirq Robotic Alignment Module • Cirq Robotic Alignment Module for robotic fine alignment of a tracked guide • Surgical instruments addressing similar use and use cases that can be inserted into above tracked guide
Robotic Application	• UI with guidance for manual pre-alignment • Communicates with Surgical Base System to provide positioning information to attached Cirq Robotic Alignment Module
Compatibility	• Different Drape from 3rd party manufacturer

Both devices are intended as image guided localization systems to position instruments. The intended use of the subject device is limited to achieving pre-planned trajectories which is a subset of the intended use of the predicate device.
The indications for use of the subject device to treat diseases where the placement of spinal screws is indicated is a subset of the indications for use of the predicate device.

The Technological Characteristics are the same as for the predicate device. Both devices

- use the same tracking technology,
- consist of a computer workstation, a tracking camera, tracked instruments
- are a combination of software, electrical and non-electrical components
- have motorized components
- communicate over the network

The various tests carried out on the subject device has been listed below:

Test	Description	Conclusion / Result
Verification of general functions	Tests regarding accurate positioning of surgical instruments to planned trajectory as well as maintenance of a position during the procedure and usefulness of the subject device in open or percutaneous, minimally invasive approaches have been conducted on a MIS Spine Training Model in a simulated clinical environment and where performed by spinal surgeons.	Verification of general functions successful. All requirements met.
General design requirements	Verification of general functions to overall design, layout and general behavior.	Verification of general design requirements successful.
Safety tests regarding risk analysis	Implementation and effectiveness of all risk control measures specified for the Cirq Robotic Alignment Module are tested and verified.	Risk control measures are effective and mitigate the associated risks.
Human factors / Usability Testing	Usability tests with surgeons and OR nurses were performed in a simulated clinical environment covering the complete clinical workflow with the Cirq Robotic Alignment Module in combination with the spine navigation applications and Brainlab navigation platform.	System is safe and effective to use.
Product safety tests	Compliance of Cirq Robotic Alignment Module including the Surgical Base System and the drape has been tested according to the following standards: • AAMI/ANSI ES60601 -1:2005/(R)2012 for medical electrical equipment - General requirements for basic safety and essential performance • IEC 60601-1-2 General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests • IEC 80601-2-77 Particular requirements for the basic safety and essential performance of for robotically assisted surgical equipment • AIM standard 7351731 Immunity Test For Exposure To Radio Frequency Identification Readers	Compliance with standards requirements demonstrated, no deviations.
Biocompatibility / Reprocessing	Material properties in relation to biocompatibility and their response to cleaning, disinfection and sterilization have been assessed and tested.	Biocompatibility assessment and reprocessing tests successful.
Environmental tests	Tests regarding adherence to RoHS, REACH and WEEE directives.	Environmental tests successful.
Compatibility tests with spinal navigation applications and Brainlab	Verification integration of Cirq Robotic Alignment Module into the spinal workflow and compatibility tests with the spinal navigation applications and Brainlab navigation platforms.	Integration and compatibility tests successful.

navigation platforms		
Mechanical tests	Mechanical stability tests, lifecycle tests and interface tests of the components of the Cirq Robotic Alignment Module from fixating the Surgical Base System to the OR table to holding surgical instruments with a defined holding force.	Mechanical tests successful.
Integration tests Robotic Application, Surgical Base System, Cirq Robotic Alignment Module and instruments.	Tested integration of Robotic Application with Surgical Base System, mounted Cirq Robotic Alignment Module and attached instruments including cybersecurity tests, verification tests ensuring that the specified braking concept for the Surgical Base System is correctly implemented and verification test on aligning to a desired position.	Integration tests Robotic Application with other components successful.
Surgical Base System firmware software verification	Tested software according to IEC 62304 and “FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”	Surgical Base System software verification successful.
Robotic Application software verification	Tested software according to IEC 62304 and “FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”	Robotic Application software verification successful.
Integration tests of sterile drape	The Cirq Robotic Alignment Module integrates a drape to ensure sterile environment to the surgical instruments. Tested that the drape matches in form, fit and function with the mechanical dimension onto the components of the Cirq Robotic Alignment Module, ensures a sterile barrier and is compatible with the navigation.	Drape integration tests successful.
Integration tests of stabilization brace	The Cirq Robotic Alignment Module integrates a stabilization brace to increase stability to the system. Tested that brace matches in form, fit and function with the mechanical dimensions of the Surgical Base System.	Stabilization brace integration tests successful.

Conclusion

The changes described above do not alter intended use or the fundamental scientific technology of the device and these changes do not present any new issues of safety and effectiveness when compared to the predicate device. Therefore, we believe that the Subject Device and the predicate are substantially equivalent.