October 27, 2022

Brainlab AG
Sadwini Suresh
QM Consultant Regulatory Affairs
Olof-Palme-Str. 9
Munich, Bavaria 81829
Germany

Re: K222966
Trade/Device Name: Cirq Arm System (2.0); Alignment System Spine
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 27, 2022
Received: September 27, 2022

Dear Sadwini Suresh:

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,

For: 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)*
K222966

Device Name
CIRQ Arm System (2.0); Alignment System Spine

Indications for Use *(Describe)*
As an accessory to the Spine & Trauma Navigation, the Alignment System Spine is intended to support the surgeon to achieve a pre-defined screw with surgical instruments during the surgical procedure. It is used for spinal screw placement procedures.

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

September 27, 2022

General Information	
Manufacturer	Brainlab AG; Olof-Palme Str.9; 81829, Munich, Germany
Establishment Registration	8043933
Trade Names	• Cirq Arm System (2.0) • Alignment System Spine
Classification Name	Orthopedic Stereotaxic Instrument
Product Code	OLO
Regulation Number	882.4560
Regulatory Class	II
Panel	Orthopedic
Predicate Device	Cirq Robotic Alignment Module – Spine (K202320)
Contact Information	
Primary Contact	Sadwini Suresh QM Consultant Regulatory Affairs Phone: +49 89 99 15 68 0 Email: regulatory.affairs@brainlab.com
Alternate Contact	Chiara Cunico Senior Manager Regulatory Affairs Phone: +49 89 99 15 68 0 Email: chiara.cunico@brainlab.com

1. Indication for Use

As an accessory to the Spine & Trauma Navigation, the Alignment System Spine is intended to support the surgeon to achieve a pre-defined screw with surgical instruments during the surgical procedure. It is used for spinal screw placement procedures.

2. Device Description

The Cirq Arm System serves as a holding and positioning system to support the surgeon in reaching a pre-defined screw trajectory with surgical instruments. It consists of a passive, semi-rigid mechatronic arm system with structural components, several modules, instrument holding and clamping mechanisms and software to guide the user.

The Cirq Arm System 2.0 is a passive mechatronic device for holding and positioning surgical instruments; it is evolved from its predecessor, the Surgical Base System 1.4 (K202320).
The Cirq Arm System 2.0 is attached to the side rail of an operating table and is intended to be used in a hospital environment, specifically in rooms which are appropriate for surgical interventions (e.g. operating rooms). The base provides external power and communication with the IGS platforms and Alignment Software Spine (if applicable, ie. if used within the active configuration).
The Cirq Arm System 2.0 can be manually positioned by releasing the brakes in the joints, using the integrated buttons. The brakes in the joints open when powered (a voltage is

supplied), and close without current. Therefore, the brakes close in case of a power failure. The brake state is visualized to the user by LED rings showing different colors for the two different brake states (open/closed) separately for each joint. The electronics and firmware are designed to be ready to operate meaning that the arm can be booted and used quickly after connecting it to the power supply.
The sterility of the device during the surgical intervention is ensured with a sterile drape, which is compatible to the Cirq Arm System 2.0 and the attached application module. The specific workflow and operating principles differ based on the attached module.

3. Substantial Equivalence

Topic/ Feature	Predicate Device (K202320)	Subject Device	Comments
Component overview	Hardware: • Surgical Base System 1.4 (Art. No. 56000A) • Cirq Robotic Alignment Module (Art. No. 56100) • Cirq Robotic Disposable Kinematic Unit (Art. No. 56102) • Cirq Robotic and Alignment Instruments (various) Software: Cirq Robotic Alignment Software 1.0	Hardware: • Cirq Arm System 2.0 (Art. No. 56500) • Cirq Robotic Alignment Module (Art. No. 56100) • Cirq Robotic Disposable Kinematic Unit (Art. No. 56102) • Cirq Robotic and Alignment Instruments (various) • Cirq Instrument Holder Module (Art. No. 56200A) • Cirq Instrument Holder Spinal Drilling (Art. No. 56202) • Accessory Package Spine Drilling for Cirq Passive (various) Software: • Alignment Software Spine 2.0	The main changes relative to the predicate is iteration of the alignment software (Cirq Robotic Alignment Software 1.0 to Alignment Software Spine 2.0, cleared in K221618), the iteration of the arm hardware (Surgical Base System 1.4 to Cirq Arm System 2.0), and the inclusion of additional hardware. The operating principle is maintained relative to the predicate, including with the additional hardware.
Arm weight	Total weight of the arm is 11.5 kg.	Total weight of the arm is 16 kg.	Increased weight compared to predicate device.
Arm dimensions	The overall length of the arm in its extended position is approximately 1200 mm.	The overall length of the arm in its extended position is approximately 1272 mm.	The reach of the arm has been increased.
Maximum payload	The defined maximum payload of the device is 1.9 kg. The holding force is supported by a technical function called Brake Boost.	The defined maximum payload of the device is 3.0 kg. This is based on the gear driven joints in joints 1-4, replacing the Brake Boost function.	Increasing the maximum payload presents no substantial differences regarding basic functionality in comparison to predicate device.

Topic/ Feature	Predicate Device (K202320)	Subject Device	Comments
Brake and joint design	The device features permanent magnetic brakes in each of the 7 axes, which ensure the holding force of the positioning arm in the closed state, and enable spatial positioning during surgical procedure. A certain stiffness is provided.	The device features permanent magnetic brakes in axes 5-7 and spring-applied brakes in axes 1-4. Additionally, axes 1-4 consist of harmonic drive gears. Due to the transmission of the gears, the system is stiffer than the previous version of the device.	Improvement in stability.

4. Performance Data

Software Verification:
Software verification was performed, verifying the software requirements through integration tests, and unit tests. Incremental test strategies have been set up after verification of the first release candidate for changes with limited scope. In this case, an impact analysis of the modifications is performed and tests to be performed are identified and planned correspondingly. That means, not all tests have to be performed but only a subset, as some of the previous tests are not affected by the change and remain therefore valid.
Software verification verifies all specifications, including SOUP items and cybersecurity.

Hardware Verification:
Hardware verification was performed, verifying the mechanical and electronic requirements, compliance to standards, and verifying the biological safety of materials and surfaces which may come in contact with the user.

Mechanical verification verifies specifications related to the mechanical subsystem, through review of CAD parts and assemblies, calculations, document review, bench testing related to holding force/payload, stiffness, mechanical safety factor, and lifecycle testing.

Electrical verification verifies specifications related to the electrical subsystem, review of documentation and schematics, and physical testing.

Biological safety was verified according to ISO 10993-1:2018.
Additional verifications have been conducted for risk-relevant specifications, user manual entries, and production steps.

5. Conclusion

The comparison of the Subject Device with the predicate device shows that the Cirq Arm System 2.0 has similar functionality, intended use and technological characteristics as the predicate device. Based on the comparison to the predicate and the performance testing conducted, the Subject Device is considered substantially equivalent to the predicate device.