November 12, 2021

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

Re: K210989
Trade/Device Name: Cirq, Cirq Robotic Alignment System, Cirq Robotic Alignment Module Cranial, Cirq Robotic Alignment Module, 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: HAW
Dated: October 12, 2021
Received: October 15, 2021

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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K210989

Device Name
Cirq, Cirq Robotic Alignment System, Cirq Robotic Alignment Module Cranial, Cirq Robotic Alignment Cranial And Spine
CIRQ Robotic alignment cranial and spine system

Indications for Use *(Describe)*
The Cirq Robotic Alignment Module is an intraoperative robotic positioning system and an accessory to compatible Brainlab IGS Cranial software applications. Using spatial information from an image guided navigation system, the Cirq Robotic Alignment Module enables the surgeon to align and hold surgical instruments according to pre-planned trajectories.

The Cirq Robotic Alignment Module is indicated for stereotactic biopsies of intracranial lesions.

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 12, 2021**

| General Information | |
|---|---|
| **Manufacturer** | Brainlab AG, Olof-Palme Str.9, 81829, Munich, Germany |
| **Applicant Details** | Chiara Cunico<br>Manager, Regulatory Affairs<br>+49899915680 |
| **Establishment Registration** | 8043933 |
| **Trade Name** | Cirq, Cirq Robotic Alignment System, Cirq Robotic Alignment Module Cranial, Cirq Robotic Alignment Cranial And Spine, CIRQ Robotic alignment cranial and spine system |
| **Classification Name** | Neurological Stereotaxic Instrument |
| **Product Code** | HAW |
| **Regulation Number** | 882.4560 |
| **Regulatory Class** | II |
| **Panel** | Neurology |
| **Predicate Device** | Medtronic Stealth Autoguide™ System (K191597) by Medtronic |
| **Reference Device** | Cirq Robotic Alignment System (K202320) by Brainlab |

## 1. Indications for Use

The Cirq Robotic Alignment Module is an intraoperative robotic positioning system and an accessory to compatible Brainlab IGS Cranial software applications. Using spatial information from an image guided navigation system, the Cirq Robotic Alignment Module enables the surgeon to align and hold surgical instruments according to pre-planned trajectories.

The Cirq Robotic Alignment Module is indicated for stereotactic biopsies of intracranial lesions.

## 2. Device Description

The subject device is intended to serve as a positing and holding device for Brainlab instruments such as drill kits, during surgical procedures.

The device consists of:

- Medical Electrical Equipment Hardware
- Medical Software
- Reprocessable Surgical Instruments, and

- Disposable Instruments

The CIRQ Robotic Alignment Module is an adapter containing a motor unit, which is attached to a user-controlled mechatronic holding arm named CIRQ Arm System. The arm is attached to the side rail of an operating table. Together they form a structure capable of holding and positioning instruments.
By using position information acquired by a compatible IGS platform via infrared tracking method, an instrument can be manually pre-aligned roughly to the region of interest by opening the brakes of the CIRQ Arm System. Following this, the tracking information is used to automatically (via the Kinematic Unit attached to the motor unit) fine align the instrument to achieve a pre-planned trajectory controlled by the CIRQ Robotic Alignment Software. After finishing the alignment, the arm with the instrument attached remains in this position and the surgeon can perform the surgical steps intended without losing the trajectory.
The position of the instruments relatively to the patient is visualized via the Cirq Robotic Alignment Software, which is running in a compatible IGS platform (see Figure 2). This software also controls and monitors the movement of the Cirq Robotic Alignment Module.

There are no variants of the device. There is only one configuration for the cranial use case.

## 3. Substantial Equivalence

| Parameters | Subject Device | Primary Predicate | Reference Device |
|---|---|---|---|
| | **Cirq** | **Medtronic Stealth Autoguide™ System (K191597)** | **Cirq Robotic Alignment System (K202320)** |
| Indications for Use/ Intended use | The Cirq Robotic Alignment Module is an intraoperative robotic positioning system and an accessory to compatible Brainlab IGS Cranial software applications. Using spatial information from an image guided navigation system, the Cirq Robotic Alignment Module enables the surgeon to align and hold surgical instruments according to pre-planned trajectories. | The Stealth Autoguide™ System is a positioning and guidance system intended for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons to guide standard neurosurgical instruments, based on a pre-operative plan and feedback from an image-guided navigation system with three-dimensional imaging software. | 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. |
| Indications for use | The Cirq Robotic Alignment Module is indicated for stereotactic biopsies of intracranial lesions. | The Stealth Autoguide™ System is a remotely-operated positioning and guidance system, indicated for any neurological condition in | The medical indications for use of the Cirq Robotic Alignment Module for spinal use is the treatment of diseases |

| Parameters | Subject Device | Primary Predicate | Reference Device |
|---|---|---|---|
| | **Cirq** | **Medtronic Stealth Autoguide™ System (K191597)** | **Cirq Robotic Alignment System (K202320)** |
| | | which the use of stereotactic surgery may be appropriate (for example, stereotactic biopsy, stereotactic EEG, laser tissue ablation, etc.). | where the placement of spinal screws is indicated. |
| Operating principle | Preoperative images (Cranial IGS)<br>Surgical planning (Cranial IGS)<br>Patient registration (Cranial IGS)<br>Guidance of instruments | Preoperative images (StealthStation)<br>Surgical planning (StealthStation)<br>Patient registration<br>Guidance of instruments | Preoperative images (Spine IGS)<br>Surgical planning<br>Patient registration (Spine IGS)<br>Guidance of instruments |
| Localization means | The infrared light is emitted by IR LEDs located in the cameras. This light is reflected by the highly reflecting markers mounted on the several tools. The camera receives the reflected light for further processing | Optical markers on tool holder | The infrared light is emitted by IR LEDs located in the cameras. This light is reflected by the highly reflecting markers mounted on the several tools. The camera receives the reflected light for further processing |
| Image-Guided | Yes | Yes (on StealthStation) | Yes |
| Planning software | Compatible with:<br>Cranial 3.1<br>Trajectory 2.5 | Compatible with:<br>S8 Cranial v1.1<br>Synergy Cranial v.3.1 | --- |
| System accuracy requirement | Under representative worstcase configuration, the Cirq Robotic Alignment with Cranial IGS Software, has demonstrated performance in 3D positional accuracy with a mean error ≤ 2.0 mm and in trajectory angle accuracy with a mean error ≤ 2.0 degrees. | Under representative worstcase configuration, the StealthStation® System with Cranial Software used with Stealth Autoguide™ System, has demonstrated performance in 3D positional accuracy with a mean error ≤ 2.0 mm and in trajectory angle accuracy with a mean error ≤ 2.0 degrees. | --- |

| Parameters | Subject Device | Primary Predicate | Reference Device |
|---|---|---|---|
| | **Cirq** | **Medtronic Stealth Autoguide™ System (K191597)** | **Cirq Robotic Alignment System (K202320)** |
| Guide position adjustment | Robotic movement | Robotic movement | Robotic movement |
| Accessories | Sterile Drape<br>Stabilization Brace<br>Cable Sets (part of Surgical Base System)<br>Instrument Calibration Matrix<br>Screwdriver for Cranial Depth Stop<br>Sterilization Tray Robotic Cranial for Cirq<br>Disposable reflective marker sphere | Sterile Drapes<br>Head Frame Adapter<br>Cable Sets | Sterile Drape<br>Stabilization Brace<br>Cable Sets (part of Surgical Base System)<br>Instrument Calibration Matrix<br>Sterilization Tray Robotic Spinal Drilling for Cirq<br>Disposable reflective marker sphere<br>Bone Drill Bits for spinal use cases |
| Real-time instrument position | Yes | Yes (on StealthStation) | Yes |
| Patient registration | Optical patient registration used from Cranial 3.1 | Optical Registration Device (via StealthStation) | Patient registration used from Spine IGS |
| Surgeon performs final instrument delivery through instrument guide | Yes | Yes | Yes |

**4. Performance Data**

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

**Performance Testing – Bench:**

Performance testing as bench testing was performed for the instrument set as part of the subject device. The specified accuracy of the instrument sets is verified using tolerance analysis and simulation tools, as well as physical test setups (Instrument and System Accuracy Test). The outcome of the system accuracy test showed that the set acceptance criteria (positional accuracy with a mean error ≤ 2.0 mm and a trajectory angle accuracy with a mean error ≤ 2.0 degrees) are met and the system is equivalent to the predicate device in its worst-case configuration. Additionally, possible impacts on the accuracy performance due to repeated sterilization of the Instrument Set were considered.

The stability of the Instrument Holder Interface was tested to ensure safe and effective connection between the Cirq Robotic Alignment Module and the Instrument Set. The locking

mechanisms of the Tracking Arrays were tested for their performance over the complete expected service life of 5 years.

Additional verification activities were focused on the Biopsy Drill Kit which consists of Guide Tube, Bone Anchor, Drill Bit and Depth Stop. It has been verified that the Bone Anchor ensures a sufficient fixation to the skull to enable a safe connection to the patients anatomy during a biopsy procedure. Furthermore, it was verified that the Bone Anchor withstands foreseeable forces which could occur during a biopsy procedure. The cutting efficiency of the Drill Bit was verified in a comparing bench test. The axial holding force of the Depth Stop was verified to ensure a safe performance during the drilling process.

**Biocompatibility Evaluation**

The biocompatibility evaluation for the Subject Device 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.

Based on the biological toxicological evaluation of existing data and test results, the device is considered to meet the requirements of ISO 10993-1 and ISO 14971 for a device with limited contact duration (≤ 24 hours) and can be considered safe and suitable for its intended use.

## 5. Conclusion

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