January 23, 2026

Point Robotics Medtech, Inc.
Brian Fang
Senior Regulatory Affairs Specialist
7f, #219, Sec.3 Beixin Rd., Xindian Dist.
New Taipei City, 231
Taiwan

Re: K252755
Trade/Device Name: "POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 29, 2025
Received: January 23, 2026

Dear Brian Fang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2026.01.23 15:58:46 -05'00'

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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K252755 |

Please provide the device trade name(s).

"POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System

Please provide your Indications for Use below.

"POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System (Kinguide RobotArm) is an accessory to the compatible "POINT" Kinguide Agile Hybrid Navigation System (Kinguide Agile) and is intended to be an intraoperative image guided localization system to support the surgeon to achieve pre-planned trajectories with surgical instruments.

"POINT" Kinguide Agile Hybrid Navigation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures.

The device is indicated for pedicle screw entry point alignment and angular orientation when using a posterior approach into T12 to S1 vertebrae (or T1-S1 vertebrae when used with the "POINT" Kinguide RobotArm), and where reference to the rigid anatomical structure can be identified by intraoperative 3D reconstruction images.

Please select the types of uses (select one or both, as applicable).

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

# 510(k) Summary

## 1. Submitter's Information

| | |
|---|---|
| Company Name | Point Robotics MedTech Inc. |
| Address | 7F., No.219, Sec.3, Beixin Rd., Xindian Dist.,<br>New Taipei City 231, Taiwan |
| Primary Contact | |
| Contact Person | Mr. Brian Fang |
| Phone | +886-2-29130272#1616 |
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| Phone | +886-2-29130272#2610 |
| Email | us.qra@pointroboticsinc.com |

## 2. Subject Device Information

| | |
|---|---|
| Proprietary/Trade Name | "POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System |
| Regulation Name | Stereotaxic Instrument |
| Regulation Number | 882.4560 |
| Product Code | OLO |
| Device Classification | II |
| Review Panel | Orthopedic |

## 3. Device Description

"POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System (*Kinguide RobotArm*) is an accessory to the compatible "POINT" Kinguide Agile Hybrid Navigation System (*Kinguide Agile*) and is intended to be an intraoperative image guided localization system to support the surgeon to achieve pre-planned trajectories with surgical instruments.

*Kinguide Agile* system is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures. *Kinguide Agile*

system is indicated for any medical condition in which the use of stereotactic spinal surgery may be appropriate, and where reference to a rigid anatomical structure can be identified relative to the digital markers of medical images (e.g. 3D C-arm) of the anatomy. *Kinguide RobotArm* is compatible with *Kinguide Agile* Software version 15.0.0 or above.

## 4. Indications for Use

"POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System (*Kinguide RobotArm*) is an accessory to the compatible "POINT" Kinguide Agile Hybrid Navigation System (*Kinguide Agile*) and is intended to be an intraoperative image guided localization system to support the surgeon to achieve pre-planned trajectories with surgical instruments.

"POINT" Kinguide Agile Hybrid Navigation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures.

The device is indicated for pedicle screw entry point alignment and angular orientation when using a posterior approach into T12 to S1 vertebrae (or T1-S1 vertebrae when used with the "POINT" Kinguide RobotArm), and where reference to the rigid anatomical structure can be identified by intraoperative 3D reconstruction images.

## 5. Identification of Legally Marketing Devices

K241130 - "POINT" Kinguide Agile Hybrid Navigation System (Primary)
K202320 - CIRQ Robotic Alignment

## 6. Comparison to the Predicate Device

| Item | Subject Device | Predicate Device (System) | Predicate Device (Accessories) |
|---|---|---|---|
| | **"POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System** | **"POINT" Kinguide Agile Hybrid Navigation System** | **CIRQ Robotic Alignment Module** |
| 510(k) number | N/A | K241130 | K202320 |
| Product Code | OLO | OLO | OLO |
| Intended Use & Indications for Use | "POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System (*Kinguide RobotArm*) is an accessory to the compatible "POINT" Kinguide Agile Hybrid Navigation System (*Kinguide Agile*) and is intended to be an intraoperative image guided localization system to support the surgeon to achieve pre-planned trajectories with surgical instruments.<br>"POINT" Kinguide Agile Hybrid Navigation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures. | "POINT" Kinguide Agile Hybrid Navigation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures.<br>The device is indicated for pedicle screw entry point alignment and angular orientation when using a posterior approach into T12 to S1 vertebrae, and where reference to the rigid anatomical structure can be identified by intraoperative 3D reconstruction images. | 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.<br>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. |

| Item | Subject Device | Predicate Device (System) | Predicate Device (Accessories) |
|---|---|---|---|
| | **"POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System** | **"POINT" Kinguide Agile Hybrid Navigation System** | **CIRQ Robotic Alignment Module** |
| | The device is indicated for pedicle screw entry point alignment and angular orientation when using a posterior approach into T12 to S1 vertebrae (or T1-S1 vertebrae when used with the "POINT" Kinguide RobotArm), and where reference to the rigid anatomical structure can be identified by intraoperative 3D reconstruction images. | | |
| Device Description | "POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System (*Kinguide RobotArm*) is an accessory to the compatible "POINT" Kinguide Agile Hybrid Navigation System (*Kinguide Agile*) and is intended to be an intraoperative image guided localization system to support the surgeon to achieve pre-planned trajectories with surgical instruments. | "POINT" Kinguide Agile Hybrid Navigation System (Kinguide Agile) is an image-guided system (IGS) that consists of an infrared navigation camera, a system workstation (computer), navigation software, and surgical instruments. This medical device system can also be referred to as an orthopedic stereotaxic instrument (OLO) according to the U.S. FDA | 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 |

| Item | Subject Device | Predicate Device (System) | Predicate Device (Accessories) |
|---|---|---|---|
| | **"POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System** | **"POINT" Kinguide Agile Hybrid Navigation System** | **CIRQ Robotic Alignment Module** |
| | *Kinguide Agile* system is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures. *Kinguide Agile* is indicated for any medical condition in which the use of stereotactic spinal surgery may be appropriate, and where reference to a rigid anatomical structure can be identified relative to the digital markers of medical images (e.g. 3D C-arm) of the anatomy.<br>*Kinguide RobotArm* is compatible with *Kinguide Agile* Software version 15.0.0 or above.<br>*Kinguide RobotArm* consists of a RobotArm Station, a Guiding Tool Set and single use accessories.<br>*Note: "POINT" Kinguide Agile Hybrid Navigation System can refer to 510(k)* | Device Classification.<br>Kinguide Agile uses optical positioning technologies to track the position of surgical instruments in relation to patient anatomy by means of Dynamic Reference Frames (DRFs) and identify the patient anatomical structure on intraoperative images (obtained using the 3D C-arm or CT*). The user loads the software to plan the surgical procedure and then registers the patient anatomy during surgery to allow the software to track the patient's anatomy and the navigable surgical instruments in real-time.<br>The software application primarily provides the stereotactic navigation function to match the coordinates of the patient anatomical structure and establishes a surgical navigation map. | 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.<br>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).<br>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 |

| Item | Subject Device | Predicate Device (System) | Predicate Device (Accessories) |
|---|---|---|---|
| | **"POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System** | **"POINT" Kinguide Agile Hybrid Navigation System** | **CIRQ Robotic Alignment Module** |
| | *Number K241130.* | The user can perform the operation according to the surgical navigation map through the use of navigable surgical instruments. During surgery, the positions of navigable surgical instruments are continuously updated on the imaging system via optical tracking.<br>*CT image DICOM file reconstructed from the 3D C-arm or the same function equipment. | 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. |
| Technical specification | **System**<br>System accuracy:<br>According to verification and validation results, *Kinguide RobotArm* used with the *Kinguide Agile* has demonstrated performance same as K241130.<br>**Accessories**<br>RobotArm Station:<br>- Degree of freedom: 6<br>- Effective payload: 5 kg (Max.) | System accuracy:<br>According to verification and validation results, *Kinguide Agile* has demonstrated performance in 3D positional accuracy with a mean positional error of ≤ 2.0 mm and mean trajectory error of ≤ 2 degrees. | CIRQ Robotic Alignment Module:<br>- Degree of freedom: 7<br>- Effective payload: 1.9 kg (Max.)<br>- Working range: 680 mm (Max.)<br>- Use a drape for robotic arm sterility<br>- Communicates with CIRQ Navigation Platform to provide positioning information<br>- Infrared passive marker-based tracking. |

| Item | Subject Device | Predicate Device (System) | Predicate Device (Accessories) |
|---|---|---|---|
| | **"POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System** | **"POINT" Kinguide Agile Hybrid Navigation System** | **CIRQ Robotic Alignment Module** |
| | - Working range: 900 mm (Max.)<br>- Use a drape for robotic arm sterility<br>- Communicates with *Kinguide Agile* system to provide positioning information.<br>- Infrared passive marker-based tracking.<br>- Use with accessories for holding surgical instruments (e.g. Guider, Guiding Cup) | | - Use with accessories for holding surgical instruments (e.g. Instrument Holder Spine for Cirq Robotics, Cirq Robotics Disposable Kinematic Unit) |
| Intended use environment | The application shall be used in an operating room. | The application shall be used in an operating room. | The application shall be used in an operating room. |
| Operator profile | The device is intended to be used by trained orthopedic surgeons, neurosurgeons, or spinal surgeons. The user should participate in a training program prior using the device. | The device is intended to be used by trained orthopedic surgeons, neurosurgeons, or spinal surgeons. The user should participate in a training program prior using the device. | The operator's profile for this devices are surgeons or their assistants having a 3D image acquisition system (such as CT or 3D C-arm) in combination with a Brainlab navigation system. All operators are performing surgeries with this system on bony structures (e.g. spine), independent of their original |

| Item | Subject Device | Predicate Device (System) | Predicate Device (Accessories) |
|---|---|---|---|
| | **"POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System** | **"POINT" Kinguide Agile Hybrid Navigation System** | **CIRQ Robotic Alignment Module** |
| | | | discipline. Therefore different kind of surgeons may perform such procedures, which also includes Orthopedic, Spinal, Trauma and Neuro surgeons. |

## Brief Substantial Equivalence Conclusion

*Kinguide RobotArm* is substantially equivalent to the listed predicate devices that share the following same technological characteristics:

- ✓ Intended Use & Indication for Use
- ✓ Instruments / Hardware Components
- ✓ Tracking technology
- ✓ System accuracy
- ✓ Intended use environment
- ✓ Intended operator

# 7. Performance Testing

The performance data, including required verification/validation, of *Kinguide RobotArm* has been carried out thoroughly both at the top level and on underlying SW/HW modules according to international standards and following U.S. FDA guidance. Verification has been conducted to demonstrate that the design specifications and the safety requirements are all met.

| Verification/Validation | Description |
|---|---|
| General Design Requirements | The design control process follows 21 CFR 820 |
| Risk Management | In compliance with ISO 14971:2019 |
| Human Factors & Usability Engineering | Usability of the system is validated in accordance with FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices" and IEC 62366-1:2015. |
| Product Safety | Compliance with standards requirements, including:<br>- IEC 60601-1 (Edition 3.2)<br>- IEC 60601-1-2 (Edition 4.1)<br>- IEC 60601-1-8 (Edition 2.2)<br>- IEC 80601-2-77 (Edition 1.1) |
| Positional Accuracy | Compliance with ASTM F2554-22 |
| Biocompatibility | Biocompatibility of those accessories that having contact with patients is evaluated in accordance with FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"" and ISO 10993-1:2018. |

| Verification/Validation | Description |
|---|---|
| Software | System software is validated in accordance with:<br>- FDA guidance "Content of Premarket Submissions for Device Software Functions"<br>- IEC 62304:2006 + A1:2015 |
| Reprocessing | Reusable accessories are validated in accordance with:<br>- FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"<br>- AAMI TIR12:2020<br>- ANSI/AAMI ST98:2022<br>- ISO 17665:2024 Sterilization of health care products – Moist heat – Requirements for the development, validation and routine control of a sterilization process for medical devices |
| Sterilization | Compliance with FDA guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile" |
| Stability & Reliability | Stability & Reliability evaluation includes:<br>- ASTM F2825-18 Standard Practice for Climatic Stressing of Packaging Systems<br>- ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems<br>- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices<br>- ISTA 3E:2017 Unitized Loads of Same Product |
| Non-clinical Performance (Accuracy) | The system has a mean accuracy of ≤2.0 mm for positional error and ≤2.0° for trajectory angle error.<br>The following verification and validation are performed in support of our performance study:<br>- Performance and Accuracy Verification Report |

## 8. Conclusion

Based on the information contained in this submission, Point Robotics believes that the subject device, "POINT" Kinguide Agile Robotic Arm Surgical Stereotactic System, is substantially equivalent to the predicate devices.