February 20, 2026

Point Robotics MedTech Inc.
Brian Fang
Senior Regulatory Affairs Specialist
7F., No.219, Sec.3, Beixin Rd., Xindian Dist.
New Taipei City, 231
Taiwan

Re: K252989
Trade/Device Name: "POINT" Kinguide Agile Hybrid Navigation System; DRF Accessories Set
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 23, 2026
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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

Shumaya Ali -S

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.	K252989

Please provide the device trade name(s).

"POINT" Kinguide Agile Hybrid Navigation System;
DRF Accessories Set

Please provide your Indications for Use below.

"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.
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Primary Contact	
Contact Person	Mr. Brian Fang
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2. Subject Device Information

Proprietary/Trade Name	"POINT" Kinguide Agile Hybrid Navigation System; DRF Accessories Set
Regulation Name	Stereotaxic Instrument
Regulation Number	882.4560
Product Code	OLO
Device Classification	II
Review Panel	Orthopedic

3. Device Description

"POINT" Kinguide Agile Hybrid Navigation System (*Kinguide Agile*) is an image-guided system (IGS) that consists of an infrared navigation camera, a system workstation, navigation software, surgical instruments and accessories, workstation cart and camera cart. This medical device system can also be referred to as an orthopedic stereotaxic instrument (OLO) according to the U.S. FDA Device Classification.

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.

The software application primarily provides the stereotactic navigation function to match the coordinates of the patient anatomical structure and establishes a surgical navigation map. 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.

*CT image DICOM file reconstructed from the 3D C-arm or the same function equipment.

DRF Accessories Set is intended to enable navigation of its compatible surgical instruments used during spinal implant procedure (e.g., pedicle screw placement) with “POINT” Kinguide Agile Hybrid Navigation System. Each DRF Accessories Set should only be used with its compatible surgical instruments.

4. Indications for Use

“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
K201189 - Stealthstation™ S8 Spine Software v1.3.0
K201327 - NavLock™ Trackers

6. Comparison to the Predicate Device

Item	Subject Device	Primary Predicate	Software/Platform Predicate	Hardware Predicate
	"POINT" Kinguide Agile Hybrid Navigation System; DRF Accessories Set	**"POINT" Kinguide Agile Hybrid Navigation System**	**Stealthstation™ S8 Spine Software v1.3.0**	**NavLock™ Trackers**
510(K) number	N/A	K241130	K201189	K201327
Product Code	OLO	OLO	OLO	OLO
Intended Use & Indications for Use	"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	"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, and where reference to the rigid anatomical structure can be identified by intraoperative 3D	The StealthStation™ System, with StealthStation™ Spine Software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the spine, can be identified relative to images of the anatomy. This can	The NavLock™ Trackers are intended to enable navigation of Medtronic instrumentation used during spinal fusion and interbody procedures with Medtronic systems utilizing STEALTH™ Technology. The NavLock™ Trackers should only be used with Medtronic instruments on Medtronic systems utilizing STEALTH™ Technology.

Item	Subject Device	Primary Predicate	Software/Platform Predicate	Hardware Predicate
	"POINT" Kinguide Agile Hybrid Navigation System; DRF Accessories Set	**"POINT" Kinguide Agile Hybrid Navigation System**	**Stealthstation™ S8 Spine Software v1.3.0**	**NavLock™ Trackers**
	reference to the rigid anatomical structure can be identified by intraoperative 3D reconstruction images.	reconstruction images.	include, but is not limited to, the following procedures: • Pedicle Screw Placement • Iliosacral Screw Placement • Interbody Device Placement	
System Accuracy Requirement	According to verification and validation results, "POINT" Kinguide Agile Hybrid Navigation System has demonstrated performance in 3D positional accuracy with a mean positional error of ≤ 2.0 mm and mean trajectory error of ≤ 2 degrees. System level accuracy testing was demonstrated on the DRF Accessories Set for use with "POINT" Kinguide Agile Hybrid Navigation System.	According to verification and validation results, "POINT" Kinguide Agile Hybrid Navigation System has demonstrated performance in 3D positional accuracy with a mean positional error of ≤ 2.0 mm and mean trajectory error of ≤ 2 degrees.	Under representative worst-case configuration, the StealthStation S8 Spine software v1.3.0, has demonstrated performance in 3D positional accuracy with a mean positional error of ≤ 2.0 mm and mean trajectory error of ≤ 2 degrees. Mean Accuracy Values (StealthAiR Spine): Positional Error – 1.01 mm Trajectory Error – 0.37 degrees Mean Accuracy Values	System level accuracy testing was demonstrated on the Navlock™ Trackers for use with StealthStation™ Systems (K171267) and MAZOR X Stealth™ Edition (K182104). Worst-case test configurations using StealthStation™ Software met the criteria of ≤2.0 mm positional error and ≤2.0° trajectory error. Rationale has been provided for the subject Navlock™ Black and Blue Trackers.

Item	Subject Device	Primary Predicate	Software/Platform Predicate	Hardware Predicate
	"POINT" Kinguide Agile Hybrid Navigation System; DRF Accessories Set	**"POINT" Kinguide Agile Hybrid Navigation System**	**Stealthstation™ S8 Spine Software v1.3.0**	**NavLock™ Trackers**
	Worst-case test configurations using *Kinguide Agile* software met the criteria of ≤2.0 mm positional error and ≤2.0° trajectory error.		(Overlapping Slices): Positional Error – 0.51 mm Trajectory Error –0.41 degrees	
Imaging Modalities	X-Ray Based Imaging	X-Ray Based Imaging	X-Ray Based Imaging	Not applicable
Rigid Anatomical Positioning Methods	Fiducial Frame is a set of optical markers mounted on a dynamic reference frame which allows user to register and track the anatomy. The reference pin is dock on the iliac crest and combines with the Fiducial Frame.	Fiducial Frame is a set of optical markers mounted on a dynamic reference frame which allows user to register and track the anatomy. The reference pin is dock on the iliac crest and combines with the Fiducial Frame.	Patient reference frame is a set of optical markers mounted on a metal frame which allows user to register and track the anatomy. The reference pin docks on the bone and combines with reference frame.	Not applicable
Registration Features	Skin Marker Registration (Referred to as Automatic Image Registration (AIR) of predicate devices)	Skin Marker Registration (Referred to as Automatic Image Registration (AIR) of predicate devices)	PointMerge Registration SurfaceMerge Registration FluoroMerge Registration Automatic 2D Image	Not applicable

Item	Subject Device	Primary Predicate	Software/Platform Predicate	Hardware Predicate
	"POINT" Kinguide Agile Hybrid Navigation System; DRF Accessories Set	**"POINT" Kinguide Agile Hybrid Navigation System**	**Stealthstation™ S8 Spine Software v1.3.0**	**NavLock™ Trackers**
			Registration Automatic 3D Image Registration StealthAiR Spine Automatic Registration	
Planning Features	Plan Entry and Target Selection 3D Model Building	Plan Entry and Target Selection 3D Model Building	Plan Entry and Target Selection 3D Model Building Deformity Planning	Not applicable
Medical Device Interfaces	Philips XperCT Siemens Artis Pheno Siemens Artis Zeego Siemens SOMATOM Definition AS Siemens Arcadis Orbic 3D GE Discovery IGS 730 GE Discovery IGS 7 OR Ziehm Imaging	Philips XperCT Siemens Artis Pheno Siemens Artis Zeego Siemens SOMATOM Definition AS Siemens Arcadis Orbic 3D GE Discovery IGS 730 GE Discovery IGS 7 OR Ziehm Imaging	O-arm Imaging System Ziehm Vision FD Vario 3D C-Arm ISO-C 3D C-Arm Ziehm Vision RFD 3D C-arm Stealth-Midas MR8 Orbic 3D C-Arm	Not applicable
View/Display Features	Look Sideways 3D View	Look Sideways 3D View	Look Sideways 3D	Not applicable

Item	Subject Device	Primary Predicate	Software/Platform Predicate	Hardware Predicate
	"POINT" Kinguide Agile Hybrid Navigation System; DRF Accessories Set	**"POINT" Kinguide Agile Hybrid Navigation System**	**Stealthstation™ S8 Spine Software v1.3.0**	**NavLock™ Trackers**
	Anatomic Orthogonal Trajectory 1 and 2 Trajectory Guidance Probe's Eye AP and Lateral Maximum Intensity Projection	Anatomic Orthogonal Trajectory 1 and 2 Trajectory Guidance Probe's Eye AP and Lateral Maximum Intensity Projection	Anatomic Orthogonal Trajectory 1 and 2 Trajectory Guidance Look Ahead Probe's Eye AP and Lateral Synthetic AP and Lateral Maximum Intensity Projection Video Input	
Software Interface (GUI)	User friendly interface with procedure task overview at home page. System tools for image adjustment, surgical planning and instrument management are contained in a left-side bar. The system information is shown on the right-side bar.	User friendly interface with procedure task overview at home page. System tools for image adjustment, surgical planning and instrument management are contained in a left-side bar. The system information is shown on the right-side bar.	Black and gray style with procedure task overview in left menu option and next/back task flow at bottom of the screen. Software controls for images, planning and instrument management are contained in a right-side bar.	Not applicable
Navigation	Using the algorithm of	Using the algorithm of	Not applicable	Not applicable

Item	Subject Device	Primary Predicate	Software/Platform Predicate	Hardware Predicate
	"POINT" Kinguide Agile Hybrid Navigation System; DRF Accessories Set	**"POINT" Kinguide Agile Hybrid Navigation System**	**Stealthstation™ S8 Spine Software v1.3.0**	**NavLock™ Trackers**
Algorithm	transformation matrices for real-time visualization & navigation of instruments relative to patient image sets	transformation matrices for real-time visualization & navigation of instruments relative to patient image sets		
Programming Language	C++	C++	C++	Not applicable
Scanner Interface Technology (to imaging devices)	CD, DVD, USB DICOM Import	CD, DVD, USB DICOM Import	Network Connectivity CD, DVD, USB DICOM Import DICOM Export	Not applicable
Localization Technology	Optical (infra-red) Manufacturer: Northern Digital Localizer: Vega	Optical (infra-red) Manufacturer: Northern Digital Localizer: Vega	Optical (infra-red) Manufacturer: Northern Digital Localizer: Vega	Not applicable
Computer Platform	Intel-based PC	Intel-based PC	Intel-based PC	Not applicable

Brief Substantial Equivalence Conclusion

"POINT" Kinguide Agile Hybrid Navigation System and DRF Accessories Set, is substantially equivalent to the listed predicate devices that share the following same technological characteristics:

- ✓ Intended Use & Indications for Use
- ✓ System Accuracy Requirement
- ✓ Imaging Modalities
- ✓ Rigid Anatomical Positioning Methods
- ✓ Registration Features
- ✓ Planning Features
- ✓ Medical Device Interfaces
- ✓ View/Display Features
- ✓ Software Interface (GUI)
- ✓ Navigation Algorithm
- ✓ Programming Language
- ✓ Scanner Interface Technology
- ✓ Localization Technology
- ✓ Computer Platform

7. Performance Testing

The performance data, including required verification/validation, of "POINT" Kinguide Agile Hybrid Navigation System and DRF Accessories Set, 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: - IEC 60601-1 (Edition 3.2)

Verification/Validation	Description
	- IEC 60601-1-2 (Edition 4.1) - IEC 60601-1-8 (Edition 2.2)
Positional Accuracy	Compliance with ASTM F2554-22 and ASTM F3107-14
Biocompatibility	Biocompatibility of those accessories that having contact with patients is evaluated in accordance with FDA Guidance "Use of International Standard ISO 10993-1" and ISO 10993-1:2018.
Software	System software is validated in accordance with: - FDA guidance "Content of Premarket Submissions for Device Software Functions" - IEC 62304:2006 + A1:2015
Reprocessing	Reusable accessories are validated in accordance with: - FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" - AAMI TIR12:2020 - ANSI/AAMI ST98:2022 - ISO 17665:2024
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: - ASTM F2825-18 Standard Practice for Climatic Stressing of Packaging Systems - ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems - ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
Non-clinical Performance (Accuracy)	The system has a mean accuracy of ≤2.0 mm for positional error and ≤2.0° for trajectory angle error. The following verification and validation are performed in support of our performance study: - Performance and Accuracy Verification Report - Cadaveric Validation Report - Compatibility and Measuring Accuracy Verification Report

Verification/Validation	Description
Clinical Performance	The system has a mean accuracy of ≤2.0 mm for positional error and ≤2.0° for trajectory angle error for pedicle screw entry point alignment and angular orientation. The following clinical data supports the Indications for Use: - Clinical Evaluation Report

8. Conclusion

Based on the information contained in this submission, Point Robotics believes that the subject device, "POINT" Kinguide Agile Hybrid Navigation System and DRF Accessories Set, is substantially equivalent to the predicate devices.