August 9, 2022

Point Robotics MedTech Inc.
Wayne Kao, Director
7F., No.219, Sec.3, Beixin Rd., Xindian Dist.
New Taipei City, 231
Taiwan

Re: K220241
Trade/Device Name: "POINT" Kinguide Robotic-Assisted Surgical System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 25, 2022
Received: d-

Dear Mr. Wayne Kao:

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, 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)*
K220241

Device Name
"POINT" Kinguide Robotic-Assisted Surgical System

Indications for Use *(Describe)*
"POINT" Kinguide Robotic-Assisted Surgical 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 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 images of the anatomy. The indications include medical procedures in which pedicle screws are implanted posteriorly into lumbar vertebrae (L1-L5) or sacral vertebrae (S1).

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

January 13, 2022

1. Submitter's Information

Submission Submitter

Company Name	Point Robotics MedTech Inc.
Address	7F., No.219, Sec.3, Beixin Rd., Xindian Dist., New Taipei City 231, Taiwan
Contact Person	Mr. Wayne Kao
Phone	866-2-29130272#165
Email	wayne.kao@pointroboticsinc.com

2. Subject Device Information

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

3. Device Description

"POINT" Kinguide Robotic-Assisted Surgical System (Kinguide Surgical System) is an orthopedic stereotaxic medical device, which consists of a hand-held robot, a passive arm, a workstation, an infrared navigation camera, navigation software, C-arm ring calibrator and surgical navigation accessories. Among them, the workstation, as the main console for controlling the hand-held robot, is equipped with a computer and control modules, which performs all operations in the surgical procedure through the computer, and transmits its information to the control modules for controlling movements of the hand-held robot. The C-arm ring calibrator and the navigation probe are used to perform registration process. The infrared navigation camera receives the spatial positioning of the patients, the hand-held robot and the surgical accessories through Dynamic Reference Frames (DRFs), and in the meantime the camera sends the data back to the workstation for monitoring stereotactic surgical operation.

The Kinguide Surgical System can assist surgeons to find surgical trajectories quickly and precisely during surgical operations. Software application in the system provides the

patient's image to match coordinates of the patient's anatomical structure, and establishes a surgical navigation map. The user can perform the operation according to the surgical navigation map with navigable tools.

4. Indications for Use

"POINT" Kinguide Robotic-Assisted Surgical 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 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 images of the anatomy. The indications include medical procedures in which pedicle screws are implanted posteriorly into lumbar vertebrae (L1-L5) or sacral vertebrae (S1).

5. Identification of Legally Marketing Devices

K201189 - StealthstationTM S8 Spine Software v1.3.0

K162309 - StealthstationTM S8 System Platforms and StealthStation Cranial Software

K160713 - Stealth-Midas System

6. Comparison to the Predicate Device

Item	Subject Device	Software Predicate	Platform Predicate	Drill System Predicate
	"POINT" Kinguide Robotic-Assisted Surgical System	Stealthstation™ S8 Spine Software v1.3.0	StealthStation™ S8 System	Stealth-Midas System
K number	N/A	K201189	K162309	K160713
Product Code	OLO	OLO	HAW, OLO, PGW	OLO
Intended Use & Indications for Use	"POINT" Kinguide Robotic-Assisted Surgical 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 any medical condition in which the use of stereotactic spinal surgery may be appropriate, and where	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	The StealthStation™ System, with StealthStation Cranial software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous surgical procedures. The StealthStationTM System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid	The Stealth-Midas System is indicated for the drilling, burring and removal of hard tissue and bone in spinal surgical procedures. Computer-assisted surgery and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of

Item	Subject Device	Software Predicate	Platform Predicate	Drill System Predicate
	"POINT" Kinguide Robotic-Assisted Surgical System	Stealthstation™ S8 Spine Software v1.3.0	StealthStation™ S8 System	Stealth-Midas System
	reference to a rigid anatomical structure can be identified relative to images of the anatomy. The indications include all medical procedures in which pedicle screws are implanted posteriorly into lumbar vertebrae (L1-L5) or sacral vertebrae (S1).	anatomical structure, such as the spine or pelvis, can be identified relative to images of the anatomy. This can include, but is not limited to, the following procedures: • Pedicle Screw Placement • Iliosacral Screw Placement • Interbody Device Placement	anatomical structure, such as the skull, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.	stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a long bone, or vertebra, can be identified relative to a CT- or MR-based model, fluoroscopic images, or digitized landmarks of the anatomy.
System Accuracy Requirement	According to verification and validation results, "POINT" Kinguide Robotic-Assisted Surgical System has demonstrated performance in 3D	Under representative worst-case configuration, the StealthStation S8 Spine software v1.3.0, has demonstrated performance in 3D positional accuracy with a mean positional	Under representative worst-case configuration, the StealthStation S8 System with StealthStation Cranial v1.0.0 Software, has demonstrated performance in 3D	Confirmed navigated instrument accuracy. Stealth-Midas integrates seamlessly with StealthStation surgical navigation solutions.

Item	Subject Device	Software Predicate	Platform Predicate	Drill System Predicate
	"POINT" Kinguide Robotic-Assisted Surgical System	Stealthstation™ S8 Spine Software v1.3.0	StealthStation™ S8 System	Stealth-Midas System
	positional accuracy with a mean positional error of ≤ 2.0 mm and mean trajectory error of ≤ 2 degrees.	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 (Overlapping Slices): Positional Error – 0.51 mm Trajectory Error –0.41 degrees	positional accuracy with a mean error ≤ 2.0 mm and in trajectory angle accuracy with a mean error ≤ 2.0 degrees.	
Imaging Modalities	X-Ray based (CT)	X-Ray Based Imaging	X-Ray based, MR based Nuclear Medicine based	Identified relative to a CT- or MR-based model

Item	Subject Device	Software Predicate	Platform Predicate	Drill System Predicate
	"POINT" Kinguide Robotic-Assisted Surgical System	Stealthstation™ S8 Spine Software v1.3.0	StealthStation™ S8 System	Stealth-Midas System
Registration Features	Surface Matching Registration Image Landmark Registration Precise Surface Registration Image Registration	PointMerge Registration SurfaceMerge Registration FluoroMerge Registration Automatic 2D Image Registration Automatic 3D Image Registration StealthAiR Spine Automatic Registration	PointMerge® registration (referred to as Landmark registrations) Tracer™ registration Touch registration (previously Touch-N-Go™) StealthAiR® registration, O-arm® registration, Mechanical based registrations (Stereotactic Localizer Registration and StarFix™ Bone Anchor Registration)	Stealth-Midas integrates seamlessly with StealthStation surgical navigation solutions.
Planning Features	Plan Entry and Target Selection 3D Model Building	Plan Entry and Target Selection 3D Model Building Deformity Planning	Plan Entry and Target selection 3D Model Building Advanced Visualization	Stealth-Midas integrates seamlessly with StealthStation surgical navigation solutions.

Item	Subject Device	Software Predicate	Platform Predicate	Drill System Predicate
	"POINT" Kinguide Robotic-Assisted Surgical System	Stealthstation™ S8 Spine Software v1.3.0	StealthStation™ S8 System	Stealth-Midas System
Medical Device Interfaces	Siemens Arcadis Varic C-Arm Siemens Arcadis Orbic C-Arm	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	Microscope Navigation: Zeiss, Leica Ultrasound Navigation: Aloka and Sonosite Medtronic O-arm® Stereotactic Frame Systems: Fischer ZD, Fischer RM, Integra CRW and Elekta Leksell Nexframe® Stereotactic System STarFix™Platform System	Stealth-Midas integrates seamlessly with StealthStation surgical navigation solutions.
View/Display Features	Look Sideways 3D View Anatomic Orthogonal Trajectory 1 and 2 Trajectory Guidance Probe's Eye AP and Lateral	Look Sideways 3D Anatomic Orthogonal Trajectory 1 and 2 Trajectory Guidance Look Ahead Probe's Eye	Ultrasound Video In, Ultrasound Overlay, 3D, 2D Anatomic Orthogonal, Trajectory 1 and 2, Target Guidance, Trajectory Guidance, Probes Eye,	Stealth-Midas integrates seamlessly with StealthStation surgical navigation solutions.

Item	Subject Device	Software Predicate	Platform Predicate	Drill System Predicate
	"POINT" Kinguide Robotic-Assisted Surgical System	Stealthstation™ S8 Spine Software v1.3.0	StealthStation™ S8 System	Stealth-Midas System
	Maximum Intensity Projection	AP and Lateral Synthetic AP and Lateral Maximum Intensity Projection Video Input	Look Ahead, Microscope Injection, Video Input, Endoscopic	
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.	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.	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.	Stealth-Midas integrates seamlessly with StealthStation surgical navigation solutions.
Programming Language	C++	C++	C++	Stealth-Midas integrates seamlessly with StealthStation surgical

Item	Subject Device "POINT" Kinguide Robotic-Assisted Surgical System	Software Predicate Stealthstation™ S8 Spine Software v1.3.0	Platform Predicate StealthStation™ S8 System	Drill System Predicate Stealth-Midas System
				navigation solutions.
Scanner Interface Technology (to imaging devices)	CD, DVD, USB DICOM Import	Network Connectivity CD, DVD, USB DICOM Import DICOM Export	Network Connectivity CD, DVD, USB DICOM Import DICOM Export	Stealth-Midas integrates seamlessly with StealthStation surgical navigation solutions.
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	Optical (infra-red) Manufacturer: Northern Digital Localizer: Vega
Computer Platform	Intel-based PC	Intel-based PC	Intel-based PC	Stealth-Midas integrates seamlessly with StealthStation surgical navigation solutions.

Item	Subject Device	Software Predicate	Platform Predicate	Drill System Predicate
	"POINT" Kinguide Robotic-Assisted Surgical System	Stealthstation™ S8 Spine Software v1.3.0	StealthStation™ S8 System	Stealth-Midas System
Drill System	The Kinguide Surgical System has a hand-held robot. The hand-held robot can be identified by the infrared navigation camera through the Robotic Base Frame (BF). It has high freedom of operation and high-precision positioning ability. It is used to position the surgical instrument connected to the end-effector of the robot.	Not Applicable	Not Applicable	The Stealth-Midas™ is a high-speed drill with a permanently attached tracker that allows for intraoperative navigation of spinal procedures using the StealthStation™ surgical navigation system.
Mechanical Support	A passive arm of this system is applied to support the hand-held robot during surgeries. It	Not Applicable	Not Applicable	A standard handpiece drill with a permanently attached tracker.

Item	Subject Device	Software Predicate	Platform Predicate	Drill System Predicate
	"POINT" Kinguide Robotic-Assisted Surgical System	Stealthstation™ S8 Spine Software v1.3.0	StealthStation™ S8 System	Stealth-Midas System
	can assist surgeons to move the hand-held robot stably and prevent from unexpected drop.			

- Brief Substantial Equivalence Discussion

"POINT" Kinguide Robotic-Assisted Surgical System and the predicates- StealthStation™ System (K201189, K162309 and K160713) are based on the following same technological elements:

- ✓ Intended Use & Indications for Use
- ✓ System Accuracy Requirement
- ✓ Imaging Modalities
- ✓ Registration Features
- ✓ Planning Features
- ✓ View/Display Features
- ✓ Software Interface (GUI)
- ✓ Programming Language
- ✓ Scanner Interface Technology
- ✓ Localization Technology
- ✓ Computer Platform

The following technological differences exist between the subject and predicate devices:

- ✓ Drill System
- ✓ Mechanical Support

There are two minor differences between the subject and predicate devices; these differences are concerning the drilling system and its mechanical support.

"POINT" Kinguide Robotic-Assisted Surgical System can provide the high-precision positioning ability and assist surgeons to move the hand-held robot stably and prevent from unexpected drop. These minor differences are addressed and evaluated in our risk management, usability engineering and cadaveric validation.

As a result, we state that the differences haven't raised further issues of safety or effectiveness but mitigate potential risk.

7. Performance Testing

The performance data, including required verification/validation, of the "POINT" Kinguide Robotic-Assisted Surgical System 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. The verification was done to demonstrate that the design specifications and the safety requirements are all met.

Verification/Validation	Description
Human Factors & Usability Engineering	Usability of the system is validated in accordance with FDA guidance of applying Human Factors and Usability Engineering to Medical Devices and IEC 62366-1:2015.
Product Safety	Compliance with standards requirements, including: - ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012 & C1:2009/(R)2012 & A2:2010/(R)2012 - IEC 60601-1:2005 +A1:2012 (Ed. 3.1) - IEC 60601-1-2:2014 - IEC 60601-1-8:2006+AMD1:2012 - IEC 80601-2-77:2019
Positional Accuracy	Compliance with ASTM F2554-18 and ASTM F3107-14
Biocompatibility	Biocompatibility of those accessories that having contact with patients is evaluated in accordance with FDA guidance for the use of international standard ISO 10993-1.
Software	System software is validated in accordance with: - FDA guidance for the Content of Premarket Submissions for Software contained in Medical Devices, 2005 - IEC 62304:2006 + A1:2015.
Reprocessing	Reusable accessories are validated in accordance with: - FDA guidance for the Reprocessing medical devices in health care settings: Validation methods and labeling, 2015. - AAMI TIR30:2011/(R)2016 - AAMI TIR12:2020
Sterilization	Compliance with FDA guidance for Submission and

Verification/Validation	Description
	Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, 2016
Stability & Reliability	Stability & Reliability evaluation includes: - Standard Practice for Climatic Stressing of Packaging Systems acc. ASTM F2825-18 - Standard Practice for Performance Testing of Shipping Containers and Systems acc. ASTM D4169-16 - Packaging for terminally sterilized medical devices acc. ISO 11607-1:2019 - Environmental testing (Vibration) acc. IEC 60068-2-6:2007 - Environmental testing (Shock) acc. IEC 60068-2-27:2008 - Degrees of protection provided by enclosures acc. IEC 60529:2013
Non-clinical Performance (Accuracy)	The system has a mean accuracy of ≦2.0 mm for location error and ≦2° 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

8. Conclusion

The information provided above supports that the “POINT” Kinguide Robotic-Assisted Surgical System is substantially equivalent to the identified predicate devices. Substantial equivalence has been demonstrated through a comparison of intended use, design, and technological characteristics, as well as performance evaluations. The “POINT” Kinguide Robotic-Assisted Surgical System can be considered substantially equivalent to the identified predicate devices.