July 17, 2023

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

Re: K230087
Trade/Device Name: "POINT" Kinguide Agile Hybrid Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 21, 2023
Received: June 21, 2023

Dear 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,

FDA Tejen D. Soni -S

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)*
K230087

Device Name
"POINT" Kinguide Agile Hybrid Navigation System

Indications for Use *(Describe)*
"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 and L1 vertebrae, and where reference to the rigid anatomical structure can be identified by intraoperative 3D reconstruction images.

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

June 21, 2023

1. Submitter's Information

Company Name	Point Robotics MedTech Inc.
Address	7F., No.219, Sec.3, Beixin Rd., Xindian Dist., New Taipei City 231, Taiwan
Contact Person (Primary)	Mr. Wayne Kao
Phone	866-2-29130272#2610
Email	wayne.kao@pointroboticsinc.com

2. Subject Device Information

Proprietary/Trade Name	"POINT" Kinguide Agile Hybrid Navigation System
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 (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 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.

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 and L1 vertebrae, and where reference to the rigid anatomical structure can be identified by intraoperative 3D reconstruction images.

5. Identification of Legally Marketing Devices

K220241 - "POINT" Kinguide Robotic-Assisted Surgical System
K201189 - Stealthstation^{TM} S8 Spine Software v1.3.0
K162309 - Stealthstation^{TM} S8 System Platforms and StealthStation Cranial Software

6. Comparison to the Predicate Device

Item	Subject Device	Primary Predicate	Software Predicate	Platform Predicate
	"POINT" Kinguide Agile Hybrid Navigation System	**"POINT" Kinguide Robotic-Assisted Surgical System**	**Stealthstation™ S8 Spine Software v1.3.0**	**StealthStation™ S8 System**
K number	N/A	K220241	K201189	K162309
Product Code	OLO	OLO	OLO	HAW, OLO, PGW
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 and L1 vertebrae, and where reference to the rigid anatomical structure	"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	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,	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 StealthStation™ System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure,

Item	Subject Device	Primary Predicate	Software Predicate	Platform Predicate
	"POINT" Kinguide Agile Hybrid Navigation System	**"POINT" Kinguide Robotic-Assisted Surgical System**	**Stealthstation™ S8 Spine Software v1.3.0**	**StealthStation™ S8 System**
	can be identified by intraoperative 3D reconstruction images.	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).	such as the spine, 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	such as the skull, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.
System Accuracy Requirement	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	According to verification and validation results, "POINT" Kinguide Robotic-Assisted Surgical System has demonstrated performance in 3D positional accuracy with a mean positional error of ≤ 2.0 mm and mean	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	Under representative worst-case configuration, the StealthStation S8 System with StealthStation Cranial v1.0.0 Software, has demonstrated performance in 3D positional accuracy with

Item	Subject Device	Primary Predicate	Software Predicate	Platform Predicate
	"POINT" Kinguide Agile Hybrid Navigation System	**"POINT" Kinguide Robotic-Assisted Surgical System**	**Stealthstation™ S8 Spine Software v1.3.0**	**StealthStation™ S8 System**
	degrees.	trajectory error of ≤ 2 degrees.	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	a mean error ≤ 2.0 mm and in trajectory angle accuracy with a mean error ≤ 2.0 degrees.
Imaging Modalities	X-Ray Based Imaging	X-Ray Based Imaging	X-Ray Based Imaging	X-Ray based, MR based Nuclear Medicine based
Rigid Anatomical Positioning Methods	Fiducial Frame Lock is a set of optical markers mounted on a dynamic reference frame	Fiducial Frame Lock is a set of optical markers mounted on a dynamic reference frame	N/A	Patient reference frame is a set of optical markers mounted on a metal frame which allows

Item	Subject Device	Primary Predicate	Software Predicate	Platform Predicate
	"POINT" Kinguide Agile Hybrid Navigation System	**"POINT" Kinguide Robotic-Assisted Surgical System**	**Stealthstation™ S8 Spine Software v1.3.0**	**StealthStation™ S8 System**
	which allows user to register and track the anatomy. The Schanz Screw (reference pin) is dock on the iliac crest and combines with the Fiducial Frame Lock.	which allows user to register and track the anatomy. The Schanz Screw (reference pin) is dock on the iliac crest and combines with the Fiducial Frame Lock.		user to register and track the anatomy. The reference pin docks on the bone and combines with reference frame.
Registration Features	Skin Marker Registration (Referred to as Automatic Image Registration (AIR) of predicate devices)	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)

Item	Subject Device	Primary Predicate	Software Predicate	Platform Predicate
	"POINT" Kinguide Agile Hybrid Navigation System	**"POINT" Kinguide Robotic-Assisted Surgical System**	**Stealthstation™ S8 Spine Software v1.3.0**	**StealthStation™ S8 System**
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	Plan Entry and Target selection 3D Model Building Advanced Visualization
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	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
View/Display Features	Look Sideways 3D View Anatomic Orthogonal Trajectory 1 and 2	Look Sideways 3D View Anatomic Orthogonal Trajectory 1 and 2	Look Sideways 3D Anatomic Orthogonal Trajectory 1 and 2	Ultrasound Video In, Ultrasound Overlay, 3D, 2D Anatomic Orthogonal,

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	Trajectory Guidance Probe's Eye AP and Lateral Maximum Intensity Projection	Trajectory Guidance Probe's Eye AP and Lateral Maximum Intensity Projection	Trajectory Guidance Look Ahead Probe's Eye AP and Lateral Synthetic AP and Lateral Maximum Intensity Projection Video Input	Trajectory 1 and 2, Target Guidance, Trajectory Guidance, Probes Eye, 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.	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.

Item	Subject Device	Primary Predicate	Software Predicate	Platform Predicate
	"POINT" Kinguide Agile Hybrid Navigation System	**"POINT" Kinguide Robotic-Assisted Surgical System**	**Stealthstation™ S8 Spine Software v1.3.0**	**StealthStation™ S8 System**
Navigation Algorithm	Using the algorithm of transformation matrices for real-time visualization & navigation of instruments relative to patient image sets	Using the algorithm of transformation matrices for real-time visualization & navigation of instruments relative to patient image sets	Not applicable	Not applicable
Programming Language	C++	C++	C++	C++
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	Network Connectivity CD, DVD, USB DICOM Import DICOM Export
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	Intel-based PC

6.1. Brief Substantial Equivalence Discussion

Kinguide Agile and the predicates- "POINT" Kinguide Robotic-Assisted Surgical System (K220241) and StealthStation™ System (K201189 and K162309) are based on the following same technological elements:

- ✓ 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 *Kinguide Agile* 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	Compliance with ISO 14971:2019
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: - IEC 60601-1:2005/CORR.1(2006)+ CORR.2(2007)+AM1(2012) - IEC 60601-1: 2012 - IEC 60601-1-2:2014 - IEC 60601-1-8:2006+AMD1:2012
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

Verification/Validation	Description
	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 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 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices acc. ASTM F1980-16
Non-clinical Performance (Accuracy)	The system has a mean accuracy of ≦2.0 mm for location 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

8. Conclusion

Based on the supporting evidence provided in this premarket notification, Point Robotics believes that the subject device, *"POINT" Kinguide Agile Hybrid Navigation System*, is substantially equivalent to the predicate devices.