FDA K230087 Point Kinguide Agile Hybrid Navigation System Instructions

Contents

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA K230087 Point Kinguide Agile Hybrid Navigation System

Product Information

Specifications

- Trade/Device Name: POINT Kinguide Agile Hybrid Navigation System
- Regulation Number: 21 CFR 882.4560
- Regulatory Class: Class II
- Product Code: OLO

Product Usage Instructions

Indications for Use

The 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. It is indicated for pedicle screw entry point alignment and angular orientation when using a posterior approach into T12 and L1 vertebrae, where reference to the rigid anatomical structure can be identified by intraoperative 3D reconstruction images.

Type of Use

This device is for Prescription Use (Part 21 CFR 801 Subpart D).

How to Use the POINT Kinguide Agile Hybrid Navigation System

Step 1: Preparing the Device

Ensure the device is properly sterilized before each use according to the manufacturer’s instructions.

Step 2: Positioning the Device

Place the device in the desired location for navigation, ensuring proper alignment with the patient’s anatomy.

Step 3: Operating the Device

Follow the on-screen instructions to navigate and locate anatomical structures accurately during the surgical procedure.

Step 4: Post-Procedure Care

After use, clean and sterilize the device again following recommended procedures to ensure safe reuse or proper disposal.

Frequently Asked Questions

Q: How often should the device be calibrated?

A: The device should be calibrated according to the manufacturer's recommendations, typically before each use or as specified in the user manual.

Q: Can the system be used for procedures other than neurosurgical and orthopedic?

A: The system is specifically designed and indicated for neurosurgical and orthopedic procedures as described in the user manual. Its use for other procedures should be verified with medical professionals.

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.

U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993
www.fda.gov

K230087 – Wayne Kao

- 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,
  Tejen D. SoniFor
  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

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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Point Robotics MedTech Inc. 510(k) Notification

Kinguide Agile
510(k) Number: K230087

510(k) Summary

June 21, 2023

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
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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

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.

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.

Identification of Legally Marketing Devices

K220241 – “POINT” Kinguide Robotic-Assisted Surgical System
K201189 – StealthstationTM S8 Spine Software v1.3.0
K162309 – StealthstationTM S8 System Platforms and StealthStation Cranial Software

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
	“POINT” Kinguide Agile	“POINT” Kinguide	The StealthStation™	The StealthStation™
	Hybrid Navigation System	Robotic-Assisted Surgical	System, with	System, with
	is intended as an aid for	System is intended as an	StealthStation Spine	StealthStation Cranial
	precisely locating	aid for precisely locating	Software, is intended as	software, is intended as
	anatomical structures in	anatomical structures in	an aid for precisely	an aid for precisely
	either open or	either open or	locating anatomical	locating anatomical
	percutaneous	percutaneous	structures in either open	structures in either open
Intended Use	neurosurgical and	neurosurgical and	or percutaneous	or percutaneous surgical
& Indications	orthopedic procedures.	orthopedic procedures.	neurosurgical and	procedures. The
for Use	The device is indicated for	The device is indicated	orthopedic procedures.	StealthStation™ System
	pedicle screw entry point	for any medical condition	Their use is indicated for	is indicated for any
	alignment and angular	in which the use of	any medical condition in	medical condition in
	orientation when using a	stereotactic spinal surgery	which the use of	which the use of
	posterior approach into	may be appropriate, and	stereotactic surgery may	stereotactic surgery may
	T12 and L1 vertebrae, and	where reference to a rigid	be appropriate, and where	be appropriate, and where
	where reference to the	anatomical structure can	reference to a rigid	reference to a rigid
	rigid anatomical structure	be identified relative to	anatomical structure,	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	images of the anatomy.	such as the spine, can be	such as the skull, can be
	intraoperative 3D	The indications include	identified relative to	identified relative to a CT
	reconstruction images.	all medical procedures in	images of the anatomy.	or MR based model,
		which pedicle screws are	This can include, but is	fluoroscopy images, or
		implanted posteriorly into	not limited to, the	digitized landmarks of
		lumbar vertebrae (L1-L5)	following procedures:	the anatomy.
		or sacral vertebrae (S1).	• Pedicle Screw	
			Placement	
			• Iliosacral Screw	
			Placement	
			• Interbody Device	
			Placement	
	According to verification	According to verification	Under representative	Under representative
	and validation results,	and validation results,	worst-case configuration,	worst-case configuration,
	Kinguide Agile has	“POINT” Kinguide	the StealthStation S8	the StealthStation S8
System	demonstrated	Robotic-Assisted Surgical	Spine software v1.3.0,	System with
Accuracy	performance in 3D	System has demonstrated	has demonstrated	StealthStation Cranial
Requirement	positional accuracy with	performance in 3D	performance in 3D	v1.0.0 Software, has
	a mean positional error of	positional accuracy with	positional accuracy with	demonstrated
	≤ 2.0 mm and mean	a mean positional error of	a mean positional error of	performance in 3D
	trajectory error of ≤ 2	≤ 2.0 mm and mean	≤ 2.0 mm and mean	positional accuracy with

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	“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

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	“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)

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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**
	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

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

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.

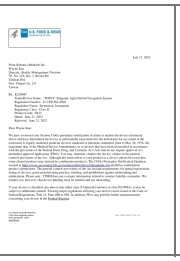
Verification/Validation	Description
General Design Requirements	The design control process follows 21 CFR 820.
Risk Management	Compliance with ISO 14971:2019
Human Factors & Usability Engineering	Usability of the system is validated in accordance with FDA guidance of applying Human Factors and Usability 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

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.

Documents / Resources

	FDA K230087 Point Kinguide Agile Hybrid Navigation System [pdf] Instructions K230087 Point Kinguide Agile Hybrid Navigation System, K230087, Point Kinguide Agile Hybrid Navigation System, Agile Hybrid Navigation System, Hybrid Navigation System, Navigation Sys tem

References

- HHS Accessibility & Section 508 | HHS.gov
- U.S. Food and Drug Administration
- U.S. Food and Drug Administration
- 510(k) Premarket Notification
- Postmarketing Safety Reporting for Combination Products | FDA
- Device Advice: Comprehensive Regulatory Assistance | FDA
- Contact Us – Division of Industry and Consumer Education (DICE) | FDA
- Medical Device Reporting (MDR): How to Report Medical Device Problems | FDA
- CDRH Learn | FDA
- User Manual