January 17, 2025

Koh Young Technology Inc.
Sooji Shin
RA Team Leader
1F, 66-27, Gwangdae 2-gil, Sejongdaewang-myeon,
Yeoju-si, Gyeonggi-do,
Republic of Korea

Re: K241333
Trade/Device Name: Geniant Cranial (Navigated Neurosurgical Positioning Robot)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: December 18, 2024
Received: December 18, 2024

Dear Sooji Shin:

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,

Yen-chih Lin -S

Digitally signed by Yen-chih Lin -S
Date: 2025.01.17 16:36:20 -05'00'

For
Adam Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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)*
K241333

Device Name
Geniant Cranial (Navigated Neurosurgical Positioning Robot)

Indications for Use *(Describe)*
The device is intended to aid in locating anatomical structures and for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons for navigating and guiding compatible surgical instruments in open or percutaneous procedures. The device is indicated for any neurosurgical procedure in which stereotactic neurosurgery may be appropriate and where reference to a rigid anatomical structure, such as the skull, can be identified relative to anatomy 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Geniant Cranial

1. Submission Applicant

a. **Company:** KOH YOUNG TECHNOLOGY Inc.
1F, 66-27, Gwangdae 2-gil, Sejongdaewang-myeon,
Yeoju-si, Gyeonggi-do, Republic of Korea

b. **Contact:** Sooji Shin
RA Team Leader
Office Phone: +82 (31) 5181-8590
Email: sj.shin@kohyoung.com

2. Date Prepared

05/09/2024

3. Device Identification

Trade/Proprietary Name: Geniant Cranial (Navigated Neurosurgical Positioning Robot)
Classification Name: Neurological stereotaxic instrument
Regulation Number(s): 882.4560
Product Code(s): HAW
Class: II
Classification Panel: Neurology

4. Legally Marketed Predicate Device(s)

Primary
Device name: ROSA ONE Brain Application
510(k) number: K200511
Manufacturer: Medtech S.A

Secondary
Device name: StealthStation S8 System Platforms and StealthStation Cranial Software
510(k) number: K162309
Manufacturer: Medtronic Navigation, Inc.

5. Device Description

Geniant Cranial is a hardware platform that supports real-time surgical navigation using medical patient images. The application software reprocesses the CT or MR images of the patient acquired before surgery.

It displays the contents on the software screen in various fluoroscopy directions (axial, sagittal and coronal). Before surgery, the surgeon can create and save one or more surgical routes to simulate. The surgeon may create and manipulate one or more 3D models of human anatomy before the surgery. During surgery, the system tracks the position of special surgical tools in the patient's anatomy and continuously updates the positions of the surgical tools in these images.
The application software can also show you how the actual position and path during surgery relate to the pre-operative plan and guide the surgeon to follow the planned trajectory. The real-time location information obtained through Geniant Cranial can help guide the surgeon's decision and the surgical route.

6. Indication for Use Statement

The device is intended to aid in locating anatomical structures and for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons for navigating and guiding compatible surgical instruments in open or percutaneous procedures. The device is indicated for any neurosurgical procedure in which stereotactic neurosurgery may be appropriate and where reference to a rigid anatomical structure, such as the skull, can be identified relative to anatomy images.

7. Substantial Equivalence Discussion

The following table compares the Geniant Cranial to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 1 - Comparison of Characteristics

Attributes	Subject Device	Primary Predicate K200511	Secondary Predicate K162309	Comparison
510(k) Number	New device	K200511	K162309	N/A
Manufacturer	KOH YOUNG TECHNOLOGY INC.	Medtech S.A	Medtronic Navigation, Inc.	N/A
Trade Name	Geniant Cranial	ROSA ONE Brain Application	StealthStation S8 System Platforms and StealthStation Cranial Software	N/A
Classification Name	Neurological stereotaxic instrument	Neurological stereotaxic instrument	Neurological stereotaxic instrument	Same
Product code	HAW	HAW	HAW	Same
Regulation Number	882.4560	882.4560	882.4560	Same
Intended Use / Indications for Use	The device is intended for use as an aid for locating anatomical structures and for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons for navigating and/or guiding	The device is intended for the spatial positioning and orientation of instruments holders or tool guides to be used by trained neurosurgeons to guide standard neurosurgical instruments (biopsy needle,	The StealthStation™ System, with StealthStation™ Cranial Software, is intended as an aid for locating anatomical structures in either open or percutaneous neurosurgical procedures. Their use is	Different

	compatible surgical instruments in open or percutaneous procedures. The device is indicated for any neurosurgical procedure in which the use of stereotactic neurosurgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to images of the anatomy.	stimulation or recording electrode, endoscope). The device is indicated for any neurosurgical procedure in which the use of stereotactic neurosurgery may be appropriate.	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 skull, can be identified relative to images of the anatomy. This can include, but is not limited to, the following cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures): • Tumor resections • General ventricular catheter placement • Pediatric ventricular catheter placement • Depth electrode, lead, and probe placement • Cranial biopsies	
Anatomical site	Head	Head	Head	Same
Sites of use	Operating rooms	Operating rooms	Operating rooms	Same
Operator	Neurosurgeon / Staff inside sterile field / Staff outside sterile field	Neurosurgeon / Clinical representative	Neurosurgeon / Clinical representative / image guidance staff	Different
System Architecture	• Console with optical sensor (Navigation HW platform) • Robot stand with robotic arm and Patient Positioning Module • Application SW • Optical markers • Probes • Head frame (O-frame kit) • Various tools mounted on robot arm to hold the surgical tools and make a path according to planning • Various optional parts and accessories for ease of use	• Robot stand with robotic arm and optical sensor • Application SW • Fiducial markers • Probe • Head frame (CRW Frame) • Various tools mounted on robot arm to hold the surgical tools and make a path according to planning • Various optional parts and accessories for ease of use	• StealthStation S8 with optical sensor (Navigation HW platform) • Application SW • Various optional parts and accessories for ease of use	Different
Principle of operation	• Intraoperative/preoperative images • Patient registration • Surgical Planning • Real-time tracking of navigated instruments • Guidance of instruments	• Intraoperative/preoperative images • Patient registration • Surgical Planning • Guidance of instruments	• Intraoperative/preoperative images • Patient registration • Surgical planning • Real-time tracking of navigated instruments	Different
Input images	• 3D preoperative exam • 3D intraoperative exam	• 3D preoperative exam • 3D intraoperative exam	• 3D preoperative exam • 3D intraoperative exam	Same

	• 2D intraoperative exam	• 2D intraoperative exam	• 2D intraoperative exam	
Integrated Planning Software	• KGuide V3.0	• ROSANNA BRAIN	• StealthStation Cranial SW	Different
Localization means	Infrared camera (Navigation Camera, manufactured by Koh Young Technology) and Robot arm relative encoders	Robot arm absolute encoders	Infrared camera (Navigation Camera, manufactured by Northerm Digital Inc.)	Different
Scanner Interface Technology (to imaging devices)	CD, DVD, USB DICOM Import/Export	CD, DVD, USB DICOM Import/Export	Network connectivity CD, DVD, USB DICOM Import/Export	Different The differences in scanner interface will not raise any safety and performanc e concerns.
Preoperative images & surgical planning features	• DICOM compliance • Merge images (multimodality image fusion capability) • Save/load planning • Plan Entry and Target Selection • 3D Model Building (Segmentation)	• DICOM compliance • Merge images (multimodality image fusion capability) • Save/load planning • Define regions of interest (ROI)	• Plan Entry and Target Selection • 3D Model Building • Advanced Visualization • Create Patient Based Anatomical Coordinate Space • Stereotactic Frame Settings • Brain Atlas: Schaltenbrand-Wahren Atlas with Talairach Grid • STarFix™ Designer Annotations	Different
Patient registration method	• Point-to-point registration with anatomical markers or skin/bone fiducials • Stereotactic Localizer Registration • Optical trace merge • Optical surface registration	• Point-to-point registration with anatomical markers or skin/bone fiducials • Stereotactic Localizer Registration • Optical surface registration	• Point-to-point registration with anatomical markers or skin/bone fiducials • Optical or electromagnetic trace merge • Intra-Op CT: Calibrated CT gantry to camera merge • Stereotactic Localizer Registration	Different
Instruments guidance Features	• Image-guided • Real-time display of the instrument position • Provide guidance for surgical instruments • Automatic instrument guide position adjustment • Surgeon carries out the final gesture through the instrument guide with the traditional surgical instrument	• Image-guided • Real-time display of the instrument position • Provide guidance for surgical instruments • Automatic instrument guide position adjustment • Surgeon carries out the final gesture through the instrument guide with the traditional surgical instrument	N/A	Same

Guidance (robot arm) controller	Axis controller for each joint Kinematic transformation between the Cartesian space and joint space Supervisor module	Axis controller for each joint Kinematic transformation between the Cartesian space and joint space Supervisor module	N/A	Same
Vigilance system	• Foot pedal	• Foot pedal	N/A	Same
Performance	• 3D positional accuracy with a mean error ≤ 1.5 mm • Trajectory angle accuracy with a mean error ≤ 2.0 degrees	• Robot arm positioning accuracy <0.75 mm RMS • Device applicative accuracy <2mm	• 3D positional accuracy with a mean error ≤ 2.0 mm • Trajectory angle accuracy with a mean error ≤ 2.0 degrees	Different
Sterility	• Non-sterile instruments • Disposable sterile drapes and covers for the robot arm	• Non-sterile and sterile instruments • Disposable sterile drapes for the robot arm and touchscreen	N/A	Different
Body Contact	Probes (skin, bone, brain tissue) Fixation pins for head fixation to a head frame (skin, bone)	Fiducial markers (skin, bone) Fixation pins and drill bits/drill (for burr holes to access the brain)	N/A	Different
Applicable standards for safety	AAMI/ANSI ES 60601-1 IEC 60601-1-2 ISO 10993-1 IEC 62304 ISO 17665-1	IEC 60601-1 IEC 60601-1-2 ISO 10993-1 IEC 62304 ISO 17665-1	AAMI/ANSI ES 60601-1 IEC 60601-1-2 IEC 62304	Same with Predicate device #1.

8. Non-Clinical Performance Data

To demonstrate safety and effectiveness of Geniant Cranial and to show substantial equivalence to the predicate device, Koh Young completed all applicable non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The Geniant Cranial passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

Table 2 -Applied standards and regulations

Standard / Regulation No.	Title
IEC 60601-1:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60825-1:2014	Safety of laser products - Part 1: Equipment classification and requirements
IEC 62471:2006	Photobiological safety of lamps and lamp systems
IEC 60601-1-6:2020	Amendment 2 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1:2020	Medical devices - Part 1: Application of usability engineering to medical devices

ANSI/AAMI HE75:2009/(R)2018	Human factors engineering – Design of medical devices
ASTM F2554-18	Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems
ISO 9283:1998	Manipulating industrial robots - Performance criteria and related test methods
AAMI TIR57:2016	Principles for Medical Device Security - Risk Management
AAMI TIR97:2019	Principles for medical device security - Postmarket risk management for device manufacturers
UL 2900-1 First Edition 2017	Standard for Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements
UL 2900-2-1 First Edition 2017	Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems
IEC 62304:2015	Medical device software - Software life cycle processes
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-4:2017	Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood
ISO 10993-5:2009	Biological evaluation of medical devices - Cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices - Skin Sensitization
SO 10993-11:2017	Biological evaluation of medical devices - Systemic Toxicity
SO 10993-23:2021	Biological evaluation of medical devices - Irritation
ASTM F2901-19	Standard Guide for Selecting Tests to Evaluate Potential Neurotoxicity of Medical Devices
USP <151>	United States Pharmacopeia - Pyrogen
ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.
AAMI TIR12:2010	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
AAMI TIR30:2011/(R)2016	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
ANSI/AAMI ST81: 2004/(R)2016	Sterilization of medical devices - Information - Processing of Resterilizable Medical Devices
ISO 11737-1:2018/AMD 1:2021	Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
ISO 11737-2:2019	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ANSI AAMI ISO 14937:2009/(R)2013	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
ISO 17665-1:2006	Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ANSI/AAMI ST79:2017 with Amendments A1:2020, A2:2020, A3:2020, A4:2020	Comprehensive guide to steam sterilization and sterility assurance in health care facilities
ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 10993-7:2008_Amd1:2019	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]
ISO 22441:2022	Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ASTM F88-15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ANSI AAMI ST77:2013/(R)2018	Containment devices for reusable medical device sterilization
ASTM F1608-21	Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)
AATCC 42-2017	Standard Test Method for Water Resistance: Impact Penetration
AATCC 127-2017(2018)e	Standard Test Method for Water Resistance: Hydrostatic Pressure
ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
ISO 7000:2019	Graphical symbols for use on equipment - Registered symbols
ISO 7010: 2019	Graphical symbols - Safety colours and safety signs - Registered safety signs
ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
IEC/TR 60878 Ed. 4.0 b:2022	Graphical symbols for electrical equipment in medical practice
IEC 60417:2002 DB	Graphical symbols for use on equipment
ISTA 3E 2017	Similar Packaged-Products in Unitized Loads of Truckload Shipment
FDA Guidance	Electromagnetic Compatibility (EMC) of Medical Devices (06/06/2022_Final)
FDA Guidance	Radio Frequency Wireless Technology in Medical Devices (08/14/2013_Final)
FDA Guidance	Applying Human Factors and Usability Engineering to Medical Devices (Feb, 2016) (Final)
FDA Guidance	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
FDA Guidance	Postmarket Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff (12/28/2016_Final)
FDA Guidance	Content of Premarket Submissions for Device Software Functions (June 2023)
FDA Guidance	Off-The-Shelf Software Use in Medical Devices
FDA Guidance	Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (09/08/2023_Final)
FDA Guidance	Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (03/17/2015_Final)
FDA Guidance	Laser Products - Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56)

9. Discussion of the Key Performance (Accuracy) Testing

To simulate the clinical procedure as closely as possible, Koh Young Technology considered all parameters that may influence the stereotactic procedure, which include the different devices, accessories, and components of Geniant Cranial, other influencing devices used in the procedure that are validated to be compatible with Geniant Cranial, and other elements of the surgical environment.

Under the representative worst-case configuration considering an actual clinical procedure, the Geniant Cranial has demonstrated performance in 3D positional accuracy with a mean error ≤1.5 mm and trajectory angle accuracy with a mean error ≤2.0 degrees. Below are the test results.

Table 3 – Accuracy Testing Result

Applied registration method	Positional Accuracy (mm)			Trajectory Angle Accuracy (degrees)		
	Mean	Standard Deviation	99% *CI** Upper Bound	Mean	Standard Deviation	99% *CI** Upper Bound
Paired Point Registration (PPR)	0.766	0.330	1.616	0.264	0.161	0.678
Bone Fiducial Registration	0.916	0.385	1.907	0.292	0.178	0.750
Tracing Registration	0.872	0.379	1.849	0.334	0.204	0.860

**CI: Confidence Interval*

10. Statement of Substantial Equivalence

Geniant Cranial has the same indications for use as the predicate devices. Any minor differences in the technological characteristics of the subject device when compared to the predicate device have been successfully evaluated through appropriate safety and performance testing which demonstrates that the subject device, when compared to the predicate device, does not raise any new questions of safety and effectiveness. Therefore, Geniant Cranial has been determined to be substantially equivalent to the predicate devices.