May 12, 2023

Waypoint Orthopedics, Inc.
Tiffini Wittwer
Regulatory Affairs
300 Applebrooke Drive
Malvern, Pennsylvania 19355

Re: K222106
Trade/Device Name: Waypoint Guided Pedicle System (GPS)
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: QWP
Dated: April 7, 2023
Received: April 12, 2023

Dear Tiffini Wittwer:

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,

Patrick Antkowiak -
S

Patrick Antkowiak
Acting 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)*
K222106

Device Name
Waypoint Guided Pedicle System (GPS)™

Indications for Use *(Describe)*
The Waypoint GPS™ is indicated for use during pedicle screw pilot hole drilling to provide visual feedback to the surgeon of changes in color to the tissue at the tip of the probe that may indicate contact with soft tissues and possible vertebral cortex perforation. The Waypoint GPS™ is indicated for use in both open and percutaneous (MIS) procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K222106

I. SUBMITTER:

Company	Waypoint Orthopedics, Inc. 300 Applebrooke Drive Malvern, PA 19355
Contact Person:	Tiffini Wittwer Regulatory Affairs Consultant Phone: 707.799.6732 E-mail: twittwer@mededge.io
Date Prepared:	April 7, 2023

II. DEVICE

Trade Name:	Waypoint Guided Pedicle System (GPS)™
Common Name:	Nerve Stimulator
Classification Name:	Neurosurgical Nerve Stimulator / Locator (21 CFR 874.1820)
Regulatory Class:	II
Product Code:	QWP

III. PREDICATE DEVICE(S)

The subject device is equivalent to the following devices:

- K201454 DSG Connect Technology

IV. DEVICE DESCRIPTION:

The Waypoint GPS™ is comprised of a single use, disposable device and a software application that is downloaded onto the provided tablet. The system is intended to provide feedback to surgeons during pilot hole drilling for pedicle screw placement. Waypoint GPS™ probe is single use disposable and consists of a handle containing electronics and a stainless-steel shaft with distal LED and fiber optics for visualizing the tissues immediately in contact with the distal end of the probe. The device produces visual signals to indicate changes in color associated with possible vertebral perforation. It uses light to provide visual alerts to indicate a change in anatomical structure to prevent placement in soft tissues or vertebral cortex perforation.

V. INDICATION FOR USE

The Waypoint GPS™ is indicated for use during pedicle screw pilot hole drilling to provide visual feedback to the surgeon of changes in color to the tissue at the tip of the probe that may indicate contact with soft tissues and possible vertebral cortex perforation. The Waypoint GPS™ is indicated for use in both open and percutaneous (MIS) procedures.

VI. SUBSTANTIAL EQUIVALENCE

The subject Waypoint GPS™ system is similar to the predicate in several ways. Both devices provide real- time feedback to the surgeon during the preparation of the pedicle screw pilot holes, alerting the surgeon when the tip of the sensor senses a change in the surrounding tissues. The subject and predicate devices have the same

intended use and use environment with similar indication for use and user interface. Both the subject device and predicate are provided as sterile, battery operated, hand-held probes comprised of similar materials. Performance testing has demonstrated that the primary technical difference (use of electrical impedance verses spectral reflectance) raises no new issues of safety and effectiveness. Thus, the subject Waypoint GPS is substantially equivalent to the predicate PediGuard.

Table 1: Substantial Equivalence Review

Item	**Waypoint Guided Pedicle System™ (Subject Device)**	**SpineGuard PediGuard With DSG Connect Technology (Predicate Device)**	**Comment**
510(k)	K222106	K201454	
Class	II	II	Same
Product Code	QWP	PDQ, ETN	Primary product code is the same
Indications for Use (IFU)	The Waypoint GPS™ is indicated for use during pedicle screw pilot hole drilling to provide visual feedback to the surgeon of changes in color to the tissue at the tip of the probe that may indicate contact with soft tissues and possible vertebral cortex perforation. The Waypoint GPS™ is indicated for use in both open and percutaneous (MIS) procedures.	The PediGuard is indicated for use during pedicle screw pilot hole drilling to provide feedback to the surgeon via visual and audible alerts that indicate a change in impedance at the tip of the probe and may indicate contact of the tip with soft tissues and possible vertebral cortex perforation. The PediGuard system is indicated for use in both open and percutaneous (MIS) surgical approaches to the spine. PediGuard is also indicated for use with fluoroscopic guidance in percutaneous (MIS) surgical approaches to the spine. The PediGuard also is specifically indicated for use in intraoperative electromyographic ("EMG") surveillance to assist in the location and evaluation of spinal nerves during surgery of the spine, by administration of low voltage electrical energy to tissues and nerves during surgery of the spine, and EMG monitoring of muscle groups associated with those nerves.	Subject device has a narrower indication for use that the predicate (does not include fluoroscopic guidance or EMG surveillance). Description of output (color versus impedance) does not change the indication for use. User validation testing demonstrates this difference does not raise new questions of safety of effectiveness.

Item	Waypoint Guided Pedicle System™ (Subject Device)	SpineGuard PediGuard With DSG Connect Technology (Predicate Device)	Comment
Output	Visual	Visual and Auditory	User validation testing of the subject device and side-by-side animal testing of the subject device and predicate device demonstrates this difference does not raise new questions of safety of effectiveness.
Connection	Software application on tablet allows for visualization	Software application on tablet allows for visualization	Same
Principles of operation	Shaft serves as bone awl and provides visual feedback indicating if device has perforated vertebral cortex	Shaft serves as bone awl and nerve locator by providing visual and auditory feedback indicating if device has perforated vertebral cortex	Pre-clinical performance testing of the subject device, and side-by-side animal testing of the subject device and predicate device demonstrates that this difference does not raise new questions of safety or effectiveness.
Technical Principles of Operation	Spectral reflectance: the electro-optical property of a material to reflect light. Photons of a specific wavelength are reflected back to a sensor. These wavelengths appear on the display tablet as the color information for the respective tissue type. • Cortical bone has lowest absorbance => more photons reflect back to sensor => lighter color • Cancellous bone has higher absorbance of green / blue & reflects red => red to dark displayed • Cortical breach (void) => highest absorbance => lack of light reflected back to sensor => dark or black color	Electrical conductivity: the property of a material to allow current flow. Electrical conductance between two electrodes is measured as current. Current is monitored in feedback circuitry that generates an output frequency in an audible range. • Cortical bone has low conductivity => lower current => low, slow signal • Cancellous bone has comparatively medium conductivity => medium signal • Periosteum and blood have high conductivity (indicates cortical breach) => larger measurement to convert => higher pitched, faster sound	Pre-clinical animal testing, including side-by-side testing of the subject device and the predicate device demonstrate that the technical difference does not raise new questions of safety or effectiveness.
Handle Shape	Gearshift Knob-Handle	Gearshift T-Handle	Same
Components	Single piece, Stainless Steel Shaft, plastic handle	Single piece, Stainless Steel Shaft, plastic handle, ceramic insulator or modular with removable handle	Same external components. Performance bench testing demonstrates differences in internal components do not raise new questions of safety of effectiveness.

Item	Waypoint Guided Pedicle System™ (Subject Device)	SpineGuard PediGuard With DSG Connect Technology (Predicate Device)	Comment
Shaft / bone awl material	17-4PH Stainless Steel	Inner electrode: 316L Stainless Steel (ASTM F138) Outer electrode and/or shaft: 304 Stainless Steel (ASTM F899), 316L Stainless Steel and/or 17-4PH (ASTM F899)	Biocompatibility testing and performance testing of the subject device demonstrates material differences do not raise new questions of safety of effectiveness.
Safety Features	Device cannot be turned off until battery exhausted. Prevents reuse of device.	Device cannot be turned off until battery exhausted. Prevents reuse of device.	Same
Internally Powered	Lithium-Ion Battery Chemistry: Li/MnO2 Max output current: 3.0mA	Lithium-Ion Battery Chemistry: Li/MnO2 Max output current: 5.5mA	Same battery type; run time of subject device is lower than predicate. Electrical safety and performance testing demonstrates difference does not raise new questions of safety of effectiveness.
Sterility	Sterile	Sterile	Same
Single Use or Reusable	Single use	Single use	Same
Distal Shaft Shape	Straight, cannulated	Curved or straight; or straight (cannulated) with removable inner starter stylet (optional) and sensory needle	Same as 1 predicate model
Dimensions	Shaft Length: 200mm Diameter of cutting edge: 4.0mm	Shaft Lengths: 120mm & 160mm Outer Diameters: 4.0mm – 5.5mm	OD is within predicate range. Performance and cadaver testing of the subject device demonstrates difference does not raise new questions of safety of effectiveness.
Circuit Board	Capacitors, Resistors and Diodes – Firmware (programmable chip) on circuit board	Capacitors, Resistors and Diodes – Firmware (programmable chip) on circuit board	Same
Anatomical Site	Spine	Spine	Same
Where used	Within a sterile field in an operating room	Within a sterile field in an operating room	Same

VII. PERFORMANCE DATA

Table 2 below lists all of the testing that has been performed on the Waypoint GPS System.

Table 2: Performance Test Summary

Test	Test Method Summary	Results
Biocompatibility Testing • Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • Material Mediated Pyrogenicity	FDA Guidance "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing and ISO 10993-1, Biological Evaluation of medical Devices Part 1: Evaluation and Testing within a risk management process. (ISO 10993-5, ISO 10993-10, 10993-11)	Passed. Non-cytotoxic, non-sensitizing, non-irritating, non-toxic, non-pyrogenic. This test is relevant in determining substantial equivalence because it demonstrates any material differences between the subject device and the predicate do not raise new questions of safety.
Insertion Force	Device shafts and finished devices were tested to demonstrate that it can complete a minimum of 15 insertions into Sawbones at a specified depth without mechanical failure similar to a standard bone awl.	Passed. Each shaft was able to successfully complete 15x insertions without mechanical failure. This test is relevant in determining substantial equivalence because it demonstrates the subject device can create multiple pilot holes during one clinical procedure and perform as a bone awl.
Torque on the shaft	Device shafts and finished devices were subjected to 15x torque on the shaft cycles. This was done to demonstrate that the device can ultimately function as a standard bone awl. Testing was performed with the tip of the shaft being at a specified depth in Sawbones and a torsion machine was used to apply force. Each device was tested repeatedly 15 times.	Passed. Each shaft was able to successfully withstand 15x torque on a shaft cycle without mechanical failure. This test is relevant in determining substantial equivalence because it demonstrates the subject device can reliably create multiple pilot holes during one clinical procedure and perform as a bone awl.
Torque on the shaft	Torque to failure testing was performed on device shafts. This testing was performed by holding both ends of the device using vices and then rotating the proximal end using a torsion machine.	Passed. Each shaft was able to successfully withstand the target torque. This test is relevant in determining substantial equivalence because it demonstrates the subject device shaft can reliably be used in creating multiple pilot holes during one clinical procedure as a bone awl.
Simulated Use Testing	Complete devices were tested for pairing of device with tablet, color calibration, color testing, and battery monitoring. Each device was tested 2 times before and after being subjected to Insertion Force and Torque on the shaft.	Passed. Each device was able to successfully complete each of the procedure steps required for intended use. This test is relevant to determining substantial equivalence because it demonstrates that the WayPoint GPS System (device and tablet) reliably performs as intended under worst case conditions. The reliability of the device communication and pairing to the tablet supports substantial equivalence of the proposed device to the predicate device with tablet communication feature.
Visualization and color	Complete devices were tested for visualization and color. This testing included monitoring the tablet screen to see if RGB value and the color changed as probe contacts with different colors and recording RGB values for each color card used.	Passed. Each device was able to successfully complete the test cycle and display correct colors and RGB values. This test is relevant in determining substantial equivalence because it demonstrates the device output (change in color) is reliably achieved, similar to the change in sound of the predicate device.

Test	Test Method Summary	Results
Electrical Safety and electromagnetic compatibility (EMC)	Testing was conducted in compliance with the IEC 60601-1 standard for safety and IEC 60601-1-2 standard for EMC.	Passed. This test is relevant in determining substantial equivalence because the subject device and predicate device both contain electrical components in their the device design.
Software Verification and Validation Testing	Testing was conducted as recommended by FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." For moderate level of concern software	Passed. This test is relevant in determining substantial equivalence because the subject device and predicate device both contain software in the device design.
Sterilization Validation	Testing was conducted in accordance with ISO 11135-1:2014 – Sterilization of Healthcare Products – Ethylene Oxide: Requirements for development, validation, and routine control of a sterilization process for medical devices. The Overkill test method was used.	Passed. This test is relevant in determining substantial equivalence because the subject device and predicate device are both terminally sterilized products.
Distribution and Aging	Devices and the package system were subjected to climactic conditioning, accelerated aging, and package performance testing as outlined in ASTM D4169-22 using Distribution Cycle 13. Individual pouches were then subjected to gross leak detection (bubble) per ASTM F2096-11, and seal strength (peel) testing per ASTM F88/F88M-21.	Passed. Insertion force, torque, simulated use, visualization, and color testing were all performed on unaged and aged devices demonstrating sterile barrier packaging and device performance reliability over time. This test is relevant in determining substantial equivalence because both devices are terminally sterilized and required to reliably perform as intended through stated expiration date.
Cadaver study	Multiple users performed device set up, calibration, pilot hole creation, and interpretation of tablet display results per the Instructions for use. Each user performed the procedure in a modified sawbone that included different colors, and a cadaver.	Passed. This test is relevant to determining substantial equivalence because it demonstrates users can perform the device procedure and correctly interpret the device output in the same procedure and intended use and the predicate.
GLP Animal Study	*In vivo* performance testing. Multiple users performed pilot hole procedures in ovine lumbar vertebrae using the GPS device and the predicate PediGuard device. Each pilot hole was planned for a specific depth (cortical bone, cancellous bone, or breach of cortical bone). Fluoroscopic CT was used to verify pilot hole depth, GPS, and PediGuard results. Additional procedures were performed in the transverse processes using GPS with direct visualization confirmation. Users reported the device tip location for both the subject device (color description) and predicate device (auditory description) locations. Data output was also recorded for each device procedure. The side-by-side comparison data was powered to >90%.	Passed. Users correctly identified GPS device tip location in all procedures (100%). Users successfully distinguished between cortical bone, cancellous bone, and a breach by the change in color and change in red, green, blue (RGB) values displayed on the table. Users correctly identified PediGuard tip location in most procedures (95%). Users were able to distinguish between cortical bone, cancellous bond, and breach by the change in cadence and pitch the predicate device emitted. The results demonstrated with statistical significance (0.050) that the subject device (WayPoint GPS System) is non-inferior to the predicate PediGuard device. The total number GPS procedures (including transverse processes) demonstrated the device performs as intended and users accurately interpret results with 95/95 confidence and reliability.

Test	Test Method Summary	Results
GLP Animal Study (continued)		This study is relevant in determining the substantial equivalence of the subject device because it provides *in vivo* objective evidence that the technical differences between the subject device and the predicate do not affect the intended use. Further the side-by-side *in vivo* testing demonstrates that user interpretation of the subject device is equivalent to the predicate device.

VIII. CONCLUSIONS

Waypoint Orthopedics considers the Guided Pedicle System™ (GPS) to be substantially equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in intended use, indication for use, anatomical sites, principles of operation, and materials. As confirmed through bench testing the Waypoint GPS™ is as safe and effective for its intended purpose as the predicate device.