May 11, 2026

Pytheas Navigation SAS
Camille Chavy
RA/QA Director
320, avenue du Prado
Marseille, 13008
France

Re: K252880
Trade/Device Name: Pytheas Your Guided Trajectory (YGT)
Regulation Number: 21 CFR 888.4560
Regulation Name: Intraoperative Surgical Angle Measurement Tool
Regulatory Class: Class II
Product Code: QWL
Dated: April 28, 2026
Received: April 28, 2026

Dear Camille Chavy:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252880

Please provide the device trade name(s).

PYTHEAS Your Guided Trajectory (YGT)

Please provide your Indications for Use below.

PYTHEAS Your Guided Trajectory is intended as an aid for use in open pedicle cannulation and screw delivery procedures in the thoracic, lumbar and sacral spine in skeletally mature patients as an augment to standard surgical technique. When used in conjunction with preoperative CT imaging and planning, the system can be used in two operating modes – Global Mode and Specific Mode:

Global Mode may be used from T10 to S1 range to provide angular guidance to the surgeon for assessing the angle of approach relative to gravity.

Specific Mode may be used from T1 to S1 range to provide angular guidance to the surgeon for assessing the angle of approach relative to digitized landmarks obtained on each vertebra

The system requires a user defined pedicle entry point, ascertained by visual analogy between intraoperative scene or intraoperative fluoroscopy compared to preoperative CT based imaging. The device is not intended to replace a surgeon's judgement or standard surgical technique methods for controlling screw placement. The system is not intended to control for patient anatomical movement.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary – K252880

I. Submitter

Pytheas Navigation SAS
320, avenue du Prado
MARSEILLE, France 13008
Phone: 33 (0) 4 86 01 06 11
Email: camille.chavy@pytheasnavigation.com

Contact Person: Camille Chavy, RA/QA Director
Date Prepared: March 10, 2026, updated May 11, 2026

II. Subject Device Name

Name of Device: PYTHEAS Your Guided Trajectory (YGT)
Common or Usual Name: Intraoperative Surgical Angle Measurement Tool
Classification Name: Intraoperative Surgical Angle Measurement Tool
Regulatory Class: II
Product Code: QWL

III. Predicate Devices

The subject device PYTHEAS YGT is substantially equivalent to the RUTHLESS SPINE RJB DEVICE (K252615).

IV. Device Description

The PYTHEAS YGT device is designed to assist the surgeon during open pedicle cannulation and screw delivery procedures in the thoracic, lumbar and sacral spine in skeletally mature patients as an augment to standard surgical technique. The device provides real-time, visual angle of approach information to the surgeon as an additional source of feedback during standard open freehand technique and helps with blind pedicle screw cannulation and screw insertion. This feedback is not intended to replace existing procedure safeguards such as intra-operative imaging and haptic feedback. The system relies on user identification of each vertebral level and entry point to provide accurate angular guidance, where system performance is relied upon once the user intraoperatively confirms entry point and vertebral level visually and radiographically against what was preoperatively defined. No clinical benefit has been demonstrated or is claimed.

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V. Indications for Use

PYTHEAS Your Guided Trajectory is intended as an aid for use in open pedicle cannulation and screw delivery procedures in the thoracic, lumbar and sacral spine in skeletally mature patients as an augment to standard surgical technique. When used in conjunction with preoperative CT imaging and planning, the system can be used in two operating modes – Global Mode and Specific Mode:

Global Mode may be used from T10 to S1 range to provide angular guidance to the surgeon for assessing the angle of approach relative to gravity.
Specific Mode may be used from T1 to S1 range to provide angular guidance to the surgeon for assessing the angle of approach relative to digitized landmarks obtained on each vertebra.

The system requires a user defined pedicle entry point, ascertained by visual analogy between intraoperative scene or intraoperative fluoroscopy compared to preoperative CT based imaging. The device is not intended to replace a surgeon's judgement or standard surgical technique methods for controlling screw placement. The system is not intended to control for patient anatomical movement.

VI. Comparison of Technological Characteristics with Predicate Devices

The subject and predicate devices use similar scientific principles and technological characteristics in the following manners:

- Pre-operative planning for pedicle screw trajectories;
- Inertial sensors determine angular orientation;
- Graphical interface with touch screens for intraoperative guidance; and
- Visual intraoperative guidance for spinal screw angular trajectory.

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Table 1: Subject device comparison with predicate devices that establish substantial equivalence.

Property	Subject Device: PYTHEAS Your Guided Trajectory	Primary Predicate: Ruthless Spine RJB (K252615)	Reference Predicate: NuVasive NVM5 (K123307)	Reference Predicate: Bolt Navigation System (K213768)	Substantially Equivalent?
Indications for Use	PYTHEAS Your Guided Trajectory is intended as an aid for use in open pedicle cannulation and screw delivery procedures in the thoracic, lumbar and sacral spine in skeletally mature patients as an augment to standard surgical technique. When used in conjunction with preoperative CT imaging and planning, the system can be used in two operating modes – Global Mode and Specific Mode: Global Mode may be used from T10 to S1 range to provide angular guidance to the surgeon for assessing the angle of approach relative to gravity. Specific Mode may be used from T1 to S1 range to provide angular guidance to the surgeon for assessing the angle of approach relative to digitized landmarks obtained on each vertebra. The system requires a user defined pedicle entry point, ascertained by visual analogy between intraoperative scene or intraoperative fluoroscopy compared to preoperative CT based imaging. The device is not intended to replace a surgeon's judgement or standard surgical technique methods	The Ruthless Spine RJB device is intended to measure the angle of surgical instruments in two planes relative to a vertical plumb line in line with gravity. It is indicated for use during lumbosacral pedicle screw implantation in conjunction with applicable spinal instrumentation and as an adjunct to fluoroscopy or intra-operative x-ray. The RJB device is not intended to replace a surgeon's judgement and has not undergone clinical evaluation. No clinical benefit has been demonstrated or is claimed.	The Guidance function is intended as an aid for use in either open or percutaneous pedicle cannulation procedures in the lumbar and sacral spine (L1-S1) of adult patients, and when used in conjunction with radiographic imaging and EMG, allows the surgeon to assess the angulation of system accessories relative to patient spinal anatomy for the creation of a cannulation trajectory for bone screw placement.	The Bolt Navigation System assists in the accurate placement of pedicle screws when used in conjunction with an intraoperative fluoroscope. It utilizes intraoperative fluoroscopic and pre- operative MRI or CT axial images to provide surgical planning and navigational telemetry relative to gravity, based on a fixed entry point ascertained by the user and validated by intraoperative fluoroscopic imaging. It is not intended to track patient position. The System is indicated for open and minimally invasive pedicle screw placement using a posterior approach in the thoracolumbar and sacral spine (T-9 to S1) where the patients' relevant rigid anatomical structures can be clearly identified on the imaging.	Yes Subject device includes additional thoracic spine, which has been assessed to the same performance metrics as lumbar and sacral spine portions.

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Property	Subject Device: PYTHEAS Your Guided Trajectory	Primary Predicate: Ruthless Spine RJB (K252615)	Reference Predicate: NuVasive NVM5 (K123307)	Reference Predicate: Bolt Navigation System (K213768)	Substantially Equivalent?
	for controlling screw placement. The system is not intended to control for patient anatomical movement.				
Clinical Use	● Requires input derived from CT. ● Intended to assist the surgeon in cannulating the pedicle based on user predefined trajectory. ● Not intended to replace a surgeon's judgment or standard surgical technique methods for controlling screw placement.	● Intended to assist the surgeon in cannulating the pedicle. ● Not intended to replace a surgeon's judgment or standard surgical technique methods for controlling screw placement.	● Requires input derived from CT, MRI, or radiographic images. ● Intended to assist the surgeon in cannulating the pedicle based on user predefined trajectory.	● Requires input derived from CT or MRI ● Intended to assist the surgeon in cannulating the pedicle based on user predefined trajectory.	Yes
Scientific Principles	● References angular sensing technology coupled with associated tracking instruments ● Uses accelerometers to sense angular measurements based on gravity by collecting 3 degrees of freedom (DOF) (rx, ry, rz) data ● Displays instrument orientation only (rotational information in the x, y, and z planes).	● References angular sensing technology coupled with associated tracking instruments ● Uses accelerometers to sense angular measurements based on gravity by collecting 2 degrees of freedom (DOF) (rx, ry) data ● Displays instrument orientation only (angular tilt in the axial and sagittal planes) with respect to gravity.	● References angular sensing technology coupled with associated tracking instruments ● Uses accelerometers to sense angular measurements based on gravity by collecting 2 degrees of freedom (DOF) (rx, ry) data	● References angular sensing technology coupled with associated tracking instruments ● Uses accelerometers to sense angular measurements based on gravity by collecting 3 degrees of freedom (DOF) (rx, ry, rz) data ● Displays instrument orientation only (rotational information in the x, y, and z planes) with respect to gravity.	Yes

Property	Subject Device: PYTHEAS Your Guided Trajectory	Primary Predicate: Ruthless Spine RJB (K252615)	Reference Predicate: NuVasive NVM5 (K123307)	Reference Predicate: Bolt Navigation System (K213768)	Substantially Equivalent?
			• Displays instrument orientation only (rotational information in the x and y planes only) with respect to gravity.		
Performance Requirements	• Pedicle screw placement rate of >95% Grade 2 or better as defined by the Gertzbein-Robbins classification system. • System angular measurement error of under ≤ 3°. • Confirmation of alignment to pre-planned trajectory. • Depends on a fixed entry point ascertained based on a fixed entry point ascertained by the user and verified by intraoperative fluoroscopic imaging.	• System angular measurement error of under ± 3°.	• System angular measurement error of under ± 3°. • Confirmation of alignment to pre-planned trajectory • Integrated with an insulated Jamshidi Needle	• System angular measurement tolerance of under ≤ 3°. • Confirmation of alignment to pre-planned trajectory • Depends on a fixed entry point ascertained by the user and validated by intraoperative fluoroscopic imaging	Yes
Conformance to Standards	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2	Yes
User Interface	Touch screen, graphical user interface	Touch screen, graphical user interface	Touch screen, graphical user interface and audio	Touch screen, graphical user interface	Yes Subject device does not provide audio feedback as it is not relevant

Property	Subject Device: PYTHEAS Your Guided Trajectory	Primary Predicate: Ruthless Spine RJB (K252615)	Reference Predicate: NuVasive NVM5 (K123307)	Reference Predicate: Bolt Navigation System (K213768)	Substantially Equivalent?
					to this procedure.
System Materials/ Biosafety	Tracking instruments composed of known and accepted (biocompatible) materials.	Tracking instruments composed of known and accepted (biocompatible) materials.	Tracking instruments composed of known and accepted (biocompatible) materials.	Tracking instruments composed of known and accepted (biocompatible) materials.	Yes
System Sterilization	As selected for individual accessories, and validated to assure an SAL 10^-6	As selected for individual accessories, and validated to assure an SAL 10^-6	As selected for individual accessories, and validated to assure an SAL 10^-6	As selected for individual accessories, and validated to assure an SAL 10^-6	Yes

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VII. Performance Data

Nonclinical and clinical testing was performed to demonstrate that the subject device is substantially equivalent to the predicate devices and to verify that the subject device meets design and performance characteristics. The subject device was subject to benchtop performance testing, clinical testing, usability testing, software verification and validation testing, electromagnetic compatibility testing, electrical safety testing, cleaning, disinfection and sterilization testing, and assessed for biocompatibility.

System procedural validation testing using a Gertzbein Robbins classification system was performed in both a clinical testing setting (Europe – 318 pedicles) and a clinically representative environment for placing pedicle screws into cadaver specimens (US – 140 pedicles). A total of 17 surgeons from the US and 5 surgeons from Europe showed a pedicle screw placement success rate > 95%.

Systema accuracy bench testing was completed using quantitative 3D measurements of system angular measurements. This testing showed system angular accuracy within ± 3° of the planned trajectory to a confidence interval of 95%.

VIII. Conclusions

Based on the indications for use, technological characteristics, and testing, the subject device has been shown to be substantially equivalent to the previously marketed predicate device.