



September 30, 2026

Brainlab SE
Esther Moreno Garcia
Manager QM
Olof-Palme-Str. 9
Munich, 81829
Germany

Re: K262257

Trade/Device Name: Spine Planning (3.0); Spine & Trauma Navigation; Alignment System Spine
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 2, 2026
Received: July 2, 2026

Dear Esther Moreno Garcia:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

Shumaya Ali -S

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.

K262257

?

Please provide the device trade name(s).

?

Spine Planning (3.0);
Spine & Trauma Navigation;
Alignment System Spine

Please provide your Indications for Use below.

?

Spine Planning:

Spine Planning is intended for pre- and intraoperative planning of open and minimally invasive spinal procedures. It displays digital patient images (CT, Cone Beam CT, MR, X-ray) and allows measurement and planning of spinal implants like screws and rods. The device is indicated for adult patients.

Spine & Trauma Navigation:

Spine & Trauma Navigation is intended as an intraoperative image-guided localization system to enable open and minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or intraoperative 2D or 3D image data.

Spine & Trauma Navigation enables computer-assisted navigation of medical image data, which can either be acquired preoperatively or intraoperatively by an appropriate image acquisition system. The software offers screw and interbody device planning and navigation with surgical instruments.

The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 3D fluoroscopic image reconstruction or 2D fluoroscopic image) and/or an image databased model of the anatomy.

Alignment System Spine:

As an accessory to the Spine & Trauma Navigation, the Alignment System Spine is intended to support the surgeon to achieve a pre-defined screw with surgical instruments during the surgical procedure. It is used for spinal screw placement procedures.

Please select the types of uses.

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

?

510(k) Summary

July 2nd , 2026

General Information	
Manufacturer	Brainlab SE; Olof-Palme-Str.9, 81829, Munich, Germany
Establishment Registration	8043933
Trade Name	Spine Planning (3.0) Spine & Trauma Navigation Alignment System Spine
Classification Name	Orthopedic Stereotaxic Instrument
Product Code	OLO
Regulation Number	882.4560
Regulatory Class	II
Panel	Orthopedic
Predicate Device(s)	K223553 – Spine Planning K221618 – Spine & Trauma Navigation, Spine Navigation, Navigation Software Spine & Trauma, Alignment System Spine, Alignment Software Spine, Cirq Arm System
Contact Information	
Primary Contact	Alternate Contact
Esther Moreno Garcia Manager QM Phone: +49 89 99 15 68 0 Email: regulatory.affairs@brainlab.com	Chiara Cunico Director QM Phone: +49 89 99 15 68 0 Email: chiara.cunico@brainlab.com

1. Indications for Use

Spine Planning

Spine Planning is intended for pre- and intraoperative planning of open and minimally invasive spinal procedures. It displays digital patient images (CT, Cone Beam CT, MR, X-ray) and allows measurement and planning of spinal implants like screws and rods. The device is indicated for adult patients.

Spine & Trauma Navigation

Spine & Trauma Navigation is intended as an intraoperative image-guided localization system to enable open and minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or intraoperative 2D or 3D image data.

Spine & Trauma Navigation enables computer-assisted navigation of medical image data, which can either be acquired preoperatively or intraoperatively by an appropriate image acquisition

system. The software offers screw and interbody device planning and navigation with surgical instruments.

The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 3D fluoroscopic image reconstruction or 2D fluoroscopic image) and/or an image databased model of the anatomy.

Alignment System Spine

As an accessory to the Spine & Trauma Navigation, the Alignment System Spine is intended to support the surgeon to achieve a pre-defined screw with surgical instruments during the surgical procedure. It is used for spinal screw placement procedures.

2. Device Description

Spine Planning

The Spine Planning software allows the user to plan spinal surgery pre-operatively or intra-operatively. The software is able to display 2D X-Ray images and 3D datasets (e.g. CT or MR scans). The software provides features for automated labelling of vertebrae and proposals for screw and rod implants, and for measurement of spinal parameters.

AI/ML algorithms are used for detection of landmarks on 2D images for vertebrae labeling and measurement; and for vertebra detection on Digitally Reconstructed Radiograph (DRR) images of 3D datasets for atlas registration (labeling of the vertebra). The AI algorithms were already cleared in K223553 and remain unchanged.

Spine Planning 3.0 introduces a sagittal alignment correction workflow which allows to plan the alignment of the spine (e.g. separation between disks) in the sagittal view of a patient avatar and then displays a rod reflecting the updated curvature of the spine. Consequently the rod can be exported in STL file.

This device can be used in combination with Spine & Trauma Navigation software during surgery, where pre-planned or intra-operatively created information can be displayed, or solely as a pre-operative tool to prepare the surgery.

Spine & Trauma Navigation

The Spine & Trauma Navigation is an image guided surgery system for navigated treatments in the fields of spine and trauma surgery, whereas the user may use image data based on CT, MR, 3D fluoroscopic image reconstruction (cone beam CT) or 2D fluoroscopic images. It offers different patient image registration methods and instrument calibrations to allow surgical navigation by using optical tracking technology. To fulfil this purpose, it consists of software, Image Guided Surgery platforms and surgical instruments.

With Spine & Trauma Navigation 3.0, it is in addition possible to visualize the pre-planned rod templates created with Spine Planning 3.0. The software is installed on a mobile or fixed Image Guided Surgery (IGS) platform (Curve, Curve Navigation, Kick 2 Navigation Station or Buzz Navigation) to support the surgeon in clinical procedures by displaying tracked instruments in patient's image data. The IGS platforms comprise of a mobile Monitor Cart or a fixed ceiling mounted display and an infrared camera for image guided surgery purposes.

Brainlab's spinal instrument portfolio includes common types of instruments used in image guided surgery procedures including patient referencing instruments, instruments for image registration, drill guides, drill bits, tracking arrays, awls and probes for open surgery, Starlink instrument adapters and arrays to allow the connection of suitable 3rd party instruments, an Instrument Calibration Matrix for calibration of instruments, sets of instruments to be used with the accessories Microscope Navigation and Cirq Arm System (Alignment System Spine), the sterile instruments Disposable Trocar Insert Pedicle Access Needle and Disposable Clip-On Remote Control and Sterilization Trays.

The device has the following accessories:

- Alignment System Spine, including the Alignment Software Spine
- Automatic Registration
- Registration Fluoro 3D
- Microscope Navigation
- Mixed Reality Spine Navigation

3. Substantial Equivalence

For the Substantial Equivalence determination, comparison of the Subject Device features with the following predicate device(s) was carried out:

	Predicate devices	Subject Device
Primary predicate	Spine Planning 2.0 (K223553)	Spine Planning 3.0
Secondary predicate	Spine & Trauma Navigation (2.0), Spine Navigation, Navigation Software Spine & Trauma, Alignment System Spine, Alignment Software Spine, Cirq Arm System (K221618)	Spine & Trauma Navigation (3.0) (also including the Alignment System Spine)

The predicate devices were chosen since they are the predecessor devices and therefore very similar to the subject device w.r.t the indications for use, technological characteristics and use cases.

Feature	Predicate Device K223553 Spine Planning 2.0	Subject Device Spine Planning 3.0	Comment
Indications for use	Spine Planning is intended for pre- and intraoperative planning of open and minimally invasive spinal procedures. It displays digital patient images (CT, Cone Beam CT, MR, X-ray) and allows measurement and planning of spinal implants like screws and rods.	Spine Planning is intended for pre- and intraoperative planning of open and minimally invasive spinal procedures. It displays digital patient images (CT, Cone Beam CT, MR, X-ray) and allows measurement and planning of spinal implants like screws and rods. The device is indicated for adult patients.	The indications for use are essentially the same. It was further specified the device is only for adults.
Version	• Spine Planning 2.0 • Universal Atlas Performer 6.0 • Universal Atlas Transfer Performer 6.0	• Spine Planning 3.0 • Universal Atlas Performer 6.0 • Universal Atlas Transfer Performer 6.0	1 st digit change on spine planning application.
Supported imaging modalities	CT, Cone Beam CT, MR, 2D X-ray images.	CT, Cone Beam CT, MR, 2D X-ray images.	Same as in predicate device.
Vertebra labelling	Labeling of vertebrae (AI/ML-based proposals for 2D X-ray and atlas-based proposals for 3D datasets). Automatic detection of cervical, thoracic, lumbar, and sacral vertebrae. Ability to adjust automatic labeling for correction if needed. Automatic labeling can be discarded and performed manually. User approval of labeling.	Labeling of vertebrae (AI/ML-based proposals for 2D X-ray and atlas-based proposals for 3D datasets). Automatic detection of cervical, thoracic, lumbar, and sacral vertebrae. Ability to adjust automatic labeling for correction if needed. Automatic labeling can be discarded and performed manually. User approval of labeling.	Instead of the midpoints, now the corner points of the vertebrae for AP and lateral X-ray images are displayed. For the lateral X-ray a patient avatar is now displayed on the page. AI algorithms unchanged.
Spinal parameter proposals	Able to add spinal parameters on X-rays based on AI/ML generated landmarks. To be manually reviewed and approved. Where AI/ML landmarks are unavailable all spinal parameters can be added manually, reviewed, and approved.	Able to add spinal parameters on X-rays based on AI/ML generated landmarks. To be manually reviewed and approved. Where AI/ML landmarks are unavailable all spinal parameters can be added manually, reviewed, and approved.	Same as in predicate device.

Feature	Predicate Device K223553 Spine Planning 2.0	Subject Device Spine Planning 3.0	Comment
Measurements	Manual measurements of angles and open angles in 2D X-ray images. Automatic screw proposals provided for cervical (lateral mass or pedicle), thoracic (pedicle), lumbar (pedicle), sacral (pedicle and alar iliac), and iliac regions.	Able to select an open angle measurement by choosing a vertebrae to measure, from a drop down menu. Automatic screw proposals provided for cervical (lateral mass or pedicle), thoracic (pedicle), lumbar (pedicle), sacral (pedicle and alar iliac), and iliac regions.	Similar functionality. Manual measurement option removed. A freely configurable measurement option is now available. For automatic proposals, some measurements have been unified and four additional measurements added.
Screw planning	Creation of manual screws. Addition of automatic screw proposals. Change of screw type (cervical and sacral regions only) User approval of all screws required. Afterwards screws are available in Spine & Trauma Navigation.	Creation of manual screws. Automatic proposals of screws in cervical and sacrum regions. Results can be reviewed and modified by user. Afterwards screws are available in Spine & Trauma Navigation.	Manual and Automatic proposed screws functionality is the same as in predicate. Only small GUI changes.
Sagittal alignment workflow	N/A	•Generation of a patient-specific avatar based on labeled 2D lateral X-ray images. •Planning of rod constructs based on spine alignment correction using the patient avatar. •Generation of a scaled rod representation corresponding to the planned correction and possible export in STL format.	New feature.

Feature	Predicate Device K221618 Spine & Trauma Navigation (2.0)	Subject Device Spine & Trauma Navigation (3.0)	Comment
Indications for use	Spine & Trauma Navigation is intended as an intraoperative image-guided localization system to enable open and minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or intraoperative 2D or 3D image data. Spine & Trauma Navigation enables computer-assisted navigation of medical image data, which can either be acquired preoperatively or intraoperatively by an appropriate image acquisition system. The software offers screw and interbody device planning and navigation with surgical instruments. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 3D fluoroscopic image reconstruction or 2D fluoroscopic image) and/or an image databased model of the anatomy.	Spine & Trauma Navigation is intended as an intraoperative image-guided localization system to enable open and minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or intraoperative 2D or 3D image data. Spine & Trauma Navigation enables computer-assisted navigation of medical image data, which can either be acquired preoperatively or intraoperatively by an appropriate image acquisition system. The software offers screw and interbody device planning and navigation with surgical instruments. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 3D fluoroscopic image reconstruction or 2D fluoroscopic image) and/or an image databased model of the anatomy.	Same compared to predicate device.
Navigation accuracy	Mean Positional Error of the placed instrument's tip ≤ 2 mm Mean Angular Error of the placed instrument's axis $\leq 2^\circ$	Mean Positional Error of the placed instrument's tip ≤ 2 mm Mean Angular Error of the placed instrument's axis $\leq 2^\circ$	Same compared to predicate device.

Feature	Predicate Device K221618 Spine & Trauma Navigation (2.0)	Subject Device Spine & Trauma Navigation (3.0)	Comment
Tracking technology	Optical tracking	Optical tracking	Same compared to predicate device.
Main SW applications	• Spine & Trauma Navigation 2.0 • Fluoro Navigation 1.0 • Instrument Setup 2.0 • Registration Software Paired Point 3.5 • Registration Software Surface Matching 1.0	• Spine & Trauma Navigation 3.0 • Fluoro Navigation 1.0 • Instrument Setup 3.0 • Registration Software Paired Point 3.5 • Registration Software Surface Matching 2.0 • Universal Atlas Performer 6.0 • Tracking Service Provider 1.0 • Camera App 3.2	Some components are unchanged, some are updated, and some new ones added. Tracking Provider App is a reimplementation of the former Tracking Service 5.0 with no new functionality and Camera App 3.2 is a reimplementation of Camera App 3.1 in HTML5. Registration applications were reimplemented in HTML5. UA 6.0 provides grey tissue information to improve view centering functionality.
Patient registration	Patient registration using paired-point and surface matching registration. Automatic Registration with intraoperative imaging or Registration Fluoro 3D.	Patient registration using paired-point and surface matching registration. Automatic Registration with intraoperative imaging or Registration Fluoro 3D.	Same methods as in predicate device. Reimplementation in HTML5.
Instrument Set up	Selection and activation of instruments. Support of instruments from multiple manufacturers. Calibration and verification of instruments prior to use.	Selection and activation of instruments. Support of instruments from multiple manufacturers, additional instruments integrated from Depuy Synthes and Highridge Medical.	Similar to predicate. Spine & Trauma Navigation 3.0 adds new compatible 3rd party instrument families compared

Feature	Predicate Device K221618 Spine & Trauma Navigation (2.0)	Subject Device Spine & Trauma Navigation (3.0)	Comment
		Calibration and verification of instruments prior to use.	to predicate device.
Navigation	Navigation of surgical instruments and spinal screw and/or cage implants.	Navigation of surgical instruments and spinal screw and/or cage implants; display of the pre-planned rod as bending template	New feature added to display a pre-planned rod generated with Spine Planning 3.0 and support for intraoperative rod bending and verification.
IGS platforms	Curve, Curve Navigation 17700, Kick 2 Navigation Station, Buzz Navigation Ceiling-mounted	Curve, Curve Navigation 17700, Curve Navigation, Kick 2 Navigation Station, Buzz Navigation Ceiling-mounted	Compared to the predicate, two Curve Navigation platforms (#17701 and #17702) have been released, with overall same design and operating principle.
Interfaces	Integrated interfaces to Magic Leap/Mixed Reality Spine Navigation and Alignment Software Spine/Cirq Arm System	Integrated interfaces to Magic Leap/Mixed Reality Spine Navigation and Alignment Software Spine/Cirq Arm System	Same compared to predicate.

4. Performance Data

The following testing was conducted on the Subject Device to establish substantial equivalence with the predicate device:

Software verification

Software verification was performed, verifying the software requirements through integration tests and unit tests. Incremental test strategies have been set up after verification of the first release candidate for changes with limited scope. In this case, an impact analysis of the modifications is performed and tests to be performed are identified and planned correspondingly. That means, not all tests have to be performed but only a subset, as some of the previous tests are not affected by the change and remain therefore valid. Software verification verifies all specifications, including SOUP items and cybersecurity.

For newly added or modified components, integration tests were carried out, in addition to the individual component verification.

Usability

A summative usability evaluation was conducted to validate the Sagittal Alignment Correction workflow in Spine Planning 3.0 and the rod bending guidance in Spine & Trauma Navigation 3.0 under simulated clinical use with 15 spine surgeons. Some improvements were identified for Spine Planning, which were implemented before final release. No usability issues were identified in the rod bending guidance. It is concluded the new features are effective for use by the intended users.

Specific for Spine Planning:

- AI/ML algorithm performance: The AI algorithms in Spine Planning 3.0 remain unchanged compared to the predicate device Spine Planning 2.0. Nevertheless, new tests have been done to evaluate the performance on the new measurements, now implemented via the UA 6.0 component. The validation demonstrated that the AI-assisted measurement outputs closely agree with gold standard expert annotations across all spinal measurement groups and a large, representative clinical dataset (~3000 X-ray images). Therefore, the subject device is equivalent to the predicate in terms of automated spinal parameter measurement performance.
- Rod contour: The purpose of this testing was to examine the rod shape generated in the Spine Planning 3.0 software. Specifically, the congruence of the rod and the rod length. A validated tool was used for the calculation of rod angles and rod lengths. The following acceptance criteria was met in all cases:
 - Rod Congruence: The absolute mean difference between the rod contour angles of the Spine Planning 3.0 rods and the rod contour angles of the rods from post-operative X-rays shall be below 10°.
 - Rod Length: The rod length proposed by Spine Planning 3.0 shall not be shorter than the rod length measured on an X-ray.
- CT-X-Ray Calibration: In the CT-X-Ray Calibration test, two calibration methods were compared to a gold standard calibration factor:
 - Calibration factor calculated by the vertebra heights based algorithm.
 - Calibration factor calculated by the vertebra center points based algorithm.

For each algorithm, the absolute percentage error between its calibration factor and the gold-standard calibration factor was calculated and analyzed independently. Both algorithms passed the test with statistical significance, demonstrating they perform as well as established methods and that it can be a potential base for e.g. distance measurements in the avatar or a rod dimension estimation.

Specific for Spine and Trauma Navigation:

- Overall accuracy: The 2D and 3D positional and angular navigation accuracy of the Spine & Trauma Navigation including the software, the platforms and the instruments was evaluated considering a realistic clinical setup and representative worst-case scenarios. The results show the following acceptance criteria are fulfilled:
 - Mean Positional Error of the placed instrument's tip ≤ 2 mm
 - Mean Angular Error of the placed instrument's axis $\leq 2^\circ$

The testing had been carried out with the predicate and is considered valid for the subject device since there are no changes to SW or HW that could impact the system accuracy. Instead, a reassessment was done using current statistical methods which reinforces the previous results. Therefore, Spine & Trauma Navigation 3.0 is considered as accurate as the predicate device.

- Rod template: A test was conducted, to test if the usage of a Rod Template can benefit during bending in comparison to a free hand rod (with pre-operative planning, not-to-scale X-Ray). Six surgeons bent 24 rods each following either a paper-printed template attached to a flipchart in order to resemble the template display on a monitor or a not-to-scale X-ray image (standard method). The mean rod contour angle difference and the similarity score met the two acceptance criteria set for the validation:
 - Mean similarity score between planned and bent rod ≤ 5 mm
 - Mean difference between planned and bent rod contour angle $\leq 10^\circ$

The additional analysis showed that there is a statistically significant difference that the template based rod bending is shown to be more accurate than the standard method with respect to the rod shape.

No clinical testing was required for the subject device since optical tracking technology in the scope of image guided surgery for the included indications for use is well established on the market.

5. Conclusion

The comparison of the Subject Device with the predicate device shows that the modified Spine Planning and Spine & Trauma Navigation have similar functionality, intended use and technological characteristics as the predicate device. Based on the comparison to the predicate and the performance testing conducted, the Subject Device is considered substantially equivalent to the predicate device.