



July 22, 2025

Brainlab AG
% Sadwini Suresh
QM Consultant
Olof-Palme-Str.9
MUNICH, 81829
GERMANY

Re: K243432

Trade/Device Name: Vascular Navigation PAD 2.0
Navigation Software Vascular PAD
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, LLZ
Dated: June 23, 2025
Received: June 23, 2025

Dear Sadwini Suresh:

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,

A handwritten signature in black ink that reads "Lu Jiang". The signature is written over a large, light blue, semi-transparent watermark of the letters "FDA".

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K243432

Device Name

Vascular Navigation PAD 2.0

Navigation Software Vascular PAD

Indications for Use (Describe)

The software supports image guidance by overlaying vessel anatomy onto live fluoroscopic images in order to navigate guidewires, catheters, stents and other endovascular devices.

The device is indicated for use by physicians for patients undergoing endovascular PAD interventions of the lower limbs including iliac vessels.

The device is intended to be used in adults.

There is no other demographic, ethnic or cultural limitation for patients.

The information provided by the software or system is in no way intended to substitute for, in whole or in part, the physician's judgment and analysis of the patient's condition.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary: K243432

July 22, 2025

General Information	
Manufacturer	Brainlab AG; Olof-Palme Str.9; 81829, Munich, Germany
Establishment Registration	8043933
Trade Name	Vascular Navigation PAD 2.0 Navigation Software Vascular PAD
Classification Name	Interventional fluoroscopic x-ray system
Product Code	OWB; LLZ
Regulation Number	892.1650
Regulatory Class	II
Panel	Radiology
Predicate Device	K222070 – EndoNaut Regulation Number: 21 CFR 892.1650; Classification Name: Image-Intensified Fluoroscopic X-ray System; Product Code: OWB; LLZ Common Name: Interventional Fluoroscopic X-ray System
Contact Information	
Primary Contact	Alternate Contact
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1. Indications for Use

The software supports image guidance by overlaying vessel anatomy onto live fluoroscopic images in order to navigate guidewires, catheters, stents and other endovascular devices.

The device is indicated for use by physicians for patients undergoing endovascular PAD interventions of the lower limbs including iliac vessels.

The device is intended to be used in adults. There is no other demographic, ethnic or cultural limitation for patients.

The information provided by the software or system is in no way intended to substitute for, in whole or in part, the physician's judgment and analysis of the patient's condition.

2. Device Description

The Subject Device is a standalone medical device software supporting image guidance in endovascular procedures of peripheral artery disease (PAD) in the lower limbs, including the iliac vessels. Running on a suitable platform and connected to an angiographic system, the Subject Device receives and displays the images acquired with the angiographic system as a video stream. It provides the ability to save and process single images out of that video stream and is able to create a vessel tree consisting of angiographic images. This allows to enrich the video stream with the saved vessel tree to continuously localize endovascular devices with respect to the vessel anatomy.

The medical device is intended for use with compatible hardware and software and must be connected to a compatible angiographic system via video connection.

3. Substantial Equivalence

Topic/ Feature	Predicate Device	Subject Device	Comments
Indications for use	EndoNaut is an image fusion software solution and computerized navigational system intended to assist X-ray fluoroscopy-guided procedures in the positioning of surgical instruments and endovascular devices. EndoNaut is indicated for use by Physicians for patients undergoing a fluoroscopy X-ray guided procedure in the chest, abdomen, pelvis, neck and lower limbs, such as aneurysm repair, artery/vein embolization, or peripheral artery disease treatment. The information provided by the software or system is in no way intended to substitute for, in whole or in part, the surgeon's judgment and analysis of the patient's condition. It is mandatory to check the real-time anatomy with a suitable imaging technique, such as a contrast-enhanced angiography, before deploying any invasive medical device.	The software supports image guidance by overlaying vessel anatomy onto live fluoroscopic images in order to navigate guidewires, catheters, stents and other endovascular devices. The device is indicated for use by physicians for patients undergoing endovascular PAD interventions of the lower limbs including iliac vessels. The device is intended to be used in adults. There is no other demographic, ethnic or cultural limitation for patients. The information provided by the software or system is in no way intended to substitute for, in whole or in part, the physician's judgment and analysis of the patient's condition.	Both devices enable image guidance by superimposing vessel anatomy onto live fluoroscopic images in order to assist in the positioning of endovascular devices. The predicate device is intended for additional use cases not covered by the device under evaluation (e.g., the combination of 3D preoperative scans and 2D intra-operative fluoroscopy data). Both devices can be used on the lower limbs. Additional intended body sites of the predicate device do not negatively affect equivalence.

Topic/ Feature	Predicate Device	Subject Device	Comments
Intended patient population	There are no limitations for patients.	The device is intended to be used in adults. There is no other demographic, ethnic or cultural limitation for patients.	Similar
Target user group	- Medical professional/ physicians - Trained vascular surgeons	- Physicians who are qualified to perform PAD interventions, with medical backgrounds in (cardio-) vascular surgery, interventional radiology, cardiology, and angiology - Steer the workflow and interact with the software using the provided human-machine interfaces (e.g., touch screen) - Trained Brainlab personnel - Responsible for product maintenance and support	Similar
Use environment	The device is intended to be used in the OR environment, installed on a hardware platform. Additionally the OR room needs to be equipped with a fluoroscopic imaging systems which is connected to the hardware platform.	The device is intended to be used in the OR environment, installed on a hardware platform. Additionally the OR room needs to be equipped with a fluoroscopic imaging systems which is connected to the hardware platform.	Identical

Topic/ Feature	Predicate Device	Subject Device	Comments
Intended site in the body	• Lower limbs • Thorax • Abdomen • Neck • Pelvis • Aorta & iliac arteries & veins	• Lower limbs including iliac arteries	Similar
Clinical condition	Procedures includes (but not limited to): • Endovascular aortic aneurysm repair (AAA & TAA) • Angioplasty • Stenting & embolization in iliac arteries and corresponding veins	Endovascular procedures of PAD including (but not limited to): • Angioplasty • Stenting	Similar Additional clinical conditions of the predicate device do not negatively affect the equivalence.
Clinical performance	Provides image guidance by overlaying vessel anatomy (based on pre-OP CTA or intra-OP angiography) onto live fluoroscopic images.	Supports image guidance by overlaying vessel anatomy onto live fluoroscopic images.	Similar The predicate device provides additional functionality for the visualization of pre-operative CTA data. The absence of this feature in the subject device does not affect the equivalence of the devices, as it does not pose any risks.

Topic/ Feature	Predicate Device	Subject Device	Comments
Functional and technical performance	• 2D-3D image registration (fusion) – only available for additional use cases • 2D-2D image registration (synchronization) • Visualization of 3D image data • Lesion measurement and planning (marking) • Intra-OP calibration (only for PAD) • Correction of vessel deformation (only available for additional use cases)	• 2D-2D image registration (synchronization) • Modality detection • Marking functionality	Similar The subject device does not provide a measuring function or registration on pre-op CT images / use of 3D image data.

Topic/ Feature	Predicate Device	Subject Device	Comments
Performance Characteristics	The clinical function of the device is “to assist X-ray fluoroscopy-guided procedures in the positioning of surgical instruments and endovascular devices.” X-ray panorama error (incl. parallax error) on in-vivo data: error mean < 10 mm (Source: 510(k) - K171829) Difference between manually corrected (“perfect panorama”) and automatically aligned panorama	The clinical function of the device is “Guiding physicians in the positioning and localization of endovascular devices (e.g. catheters) relative to overlaid vessel anatomy.” Critical performance characteristics to fulfill the clinical function are identified as: - Displaying video stream (added video latency ≤ 250 ms) - Overlaying vessel anatomy (2D deviation for roadmapping ≤ 5 mm).	Similar Both device provide a clinical function to guide physicians in positioning and localization of endovascular devices relative to overlaid vessel anatomy. Both devices define their critical performance characteristics by accuracy requirements on this functionality. The acceptance criteria defined by the Subject Device is stricter than by the predicate device. This does not pose any safety or performance risks.

Topic/ Feature	Predicate Device	Subject Device	Comments
Input data	- DICOM Images - EndoNaut archive produced with Therenva EndoSize Planning Software. - C-Arm video stream - User command via touchscreen interaction	- Patient name - Video data from accessory or compatible medical devices - User command via touchscreen interaction	Identical
Export	- Take and export snapshots. - Export panoramas in case of PAD module.	- Patient image data (e.g., panoramas) - Screenshots	Identical

Hardware compatibility	EndoNaut system consists of a software part that carries the medical features and technologies that are controlled and a hardware part that enables the medical device to be used in accordance with its intended purpose. The hardware part can be: - the EndoNaut Workstation or - a computer meeting the minimum Hardware and Software requirements for EndoNaut standalone SW or EndoNaut Server. The Hardware part must be compliant with the US regulations. Basic requirements are: - Operating System: Windows 10 64bits - Processor: Intel i7-6600U (2.6GHz) or higher - RAM: 16 GB or higher - Graphics: integrated Intel HD Graphics 520 or better dedicated graphic card - Hard Drive: SSD recommended, 2 GB free space plus 500 MB free space per case - Screens: two displays, tactile recommended for secondary display - Screen resolution: 1920*1080 for main display, 1366*768 for secondary display	Compatible with a frame grabber based environment, with a set on the following minimum requirements on the hardware: - Compatibility with Brainlab Origin Data Management (ODM) Version 3.2 - Yuan FrameGrabber compatible with YuanServer = 1.0 - Touchscreen - Display resolution at least 1920 x 1080 - CPU Physical cores = 8 - RAM = 24GB - NVIDIA GPU = 8 GB - SSD with 1GB storage available	Similar Both devices run on hardware platforms that are intended to be used in the OR. And both devices haven an open hardware compatibility regulated with a set of requirements on the hardware. Additional deployment method on a server of the EndoNaut device does not influence equivalence. Differences in requirements on the hardware (e.g., graphics card) do not affect the safety and performance of the devices.
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Topic/ Feature	Predicate Device	Subject Device	Comments
	- Minimal screen size: 27" (main display) and 15.6" (secondary display) - Digital video input		
User interaction	- Standalone SW: via touch screen - No interface for server application; Interface is provided by a client connected via communication protocol	- Touch screen - Remote control	Similar
Operating System	Windows 10 / 64 bits	Windows 10 / 64 bits	Identical

Topic/ Feature	Predicate Device	Subject Device	Comments
Algorithm method	- Image stitching: Proposal of alignment with manual adjustment possibilities 2D-2D image registration (overlay alignment): Manual initial first registration, automatic computation and manual validation. Artificial Intelligence / Machine Learning algorithms used in: - Registration 3D/2D – Automatic or manual initialization, automatic computation and manual validation (not in this use case) - Motion detection - Contrast agent injection detection	- Semi-automated modality detection differentiates between fluoroscopic and angiographic images with manual adjustment possibilities - Image stitching: Proposal of alignment with manual adjustment possibilities 2D-2D image registration (overlay alignment): Semi-automated registration once, afterwards automated alignment can be triggered manually with manual adjustment possibilities Artificial Intelligence / Machine Learning is not used by the Subject Device.	Similar Both devices provide algorithms for 2D-2D image registration and image stitching aiming for the clinical performance. Other additional algorithms in the predicate device, such as the 3D/2D image fusion, are not intended to be used for the relevant clinical conditions and intended body site (lower limb). Both, the modality detection algorithm of the subject device and the contrast agent injection detection of the predicate device identify images with contrast agent.

Topic/ Feature	Predicate Device	Subject Device	Comments
Software feature: Image capturing and assignment	Capturing of fluoroscopic and angiographic images out of a continuous video stream must be done manually and stage by stage keeping the same C-Arm orientation per stage. Contrast agent injection detection. The result can be adjusted manually.	Capturing of fluoroscopic and angiographic images out of a continuous video stream must be done manually and stage by stage keeping the same C-Arm orientation per stage. Modality categorization of images (fluoroscopic or angiographic) is done by a semi-automated software algorithm or can be done manually. The result can be adjusted manually.	Similar Both, the modality detection algorithm of the subject device and the contrast agent injection detection of the predicate device identify images with contrast agent.
Software feature: Stitching of images for vessel tree / Panorama	Alignment of overlapping images for stitching is performed by a software algorithm. The result can be adjusted manually. Panorama consists out of several 2D fluoroscopic and angiographic images.	Alignment of overlapping images for stitching is performed by a software algorithm. The result can be adjusted manually. Panorama consists out of several 2D angiographic images (Angiographical Panorama).	Identical Both devices create an overview of the vessel anatomy (panorama creation / angiographic panorama)

Topic/ Feature	Predicate Device	Subject Device	Comments
Software feature: Roadmapping / 2D-2D Registration	Display 2D-2D fusion: 2D pre-op angiographic overlay on per-op 2D fluoroscopy. Synchronization between current per-op 2D fluoroscopy and 2D fluoroscopy from recorded panorama.	Roadmapping: Overlay of previously captured vessel anatomy on live fluoroscopic images. Alignment is performed by aligning live fluoroscopic image and captured underlying fluoroscopic image.	Similar Both devices are designed to enrich live fluoroscopic images with previously acquired images of the vessel anatomy, allowing for the localization of endovascular devices. Both device align the overlay using live and captured fluoroscopic image. Both devices use the overview for image fusion and navigation (2D-2D fusion / Roadmapping/ Fluoroscopy augmentation).
Software feature: Marking	Marking on live image and panorama	Marking on previously captured angiographic images	Similar

Topic/ Feature	Predicate Device	Subject Device	Comments
Software feature: Dynamic update on C- arm / table / patient motion	Automatic motion detection Registration: Automatic/manual initialization and manual user validation.	No automatic motion detection Registration: Semi-automated by manual initialization and manual user validation.	Similar Both devices provide an automated way of performing the registration (overlay alignment). Subject device does not provide an automatic motion detection which does not pose any additional risk.

4. Performance Data

The Subject Device has been verified and validated according to Brainlab processes for product design and development. A high-level explanation of the testing provided in this submission for the Subject Device is provided below. For more details, please refer to the document Verification and Performance Bench Testing Summary.

The following imaging devices providing verification performance data were either operated in clinical settings without control of detailed imaging parameters (according to the standard procedure of the respective physician / hospital) or configured using standard manufacturer-provided settings of vascular profiles:

Manufacturer	Model	Imaging mode	Anatomical locations
GE	OEC Elite CFD	Vascular Profile	Iliac communis and lower
Siemens	Cios Spin	Vascular – Vascular Extremity	
Ziehm	Vision RFD 3D	Vascular Workflow	
Philips	Azurion	Vascular X-ray protocol	
	Zenition	Examination Type Procedure: Vascular / Leg	

These devices represent commonly used systems in endovascular PAD procedures and are equipped with state-of-the-art imaging technology. A key requirement for these devices is the capability to generate subtracted angiographic images, ensuring they have at least the basic vascular features.

The available imaging parameters are configured and managed by the imaging device manufacturer to optimize the balance between image quality and radiation exposure. This is achieved through automated features such as kV modulation, brightness control, and exposure regulation. All imaging device manufacturers must comply with the same regulatory standards, which define acceptable radiation dose limits and image quality requirements. Consequently, the contrast and brightness of images produced by compliant systems are generally equivalent.

Compatibility to imaging devices is not limited to above mentioned systems. A set of minimum imaging system requirement is communicated to the user within the software user guide.

Software verification:

Software verification has been performed on software level, verifying the software requirements through integration tests as well as GUI tests and Unit tests.

Latency Tests:

The objective of this test was to evaluate the occurring added video latency of the navigation assistance in a realistic system setup. It was evaluated if individual components of the setup add critical video latency to the transmission chain (imaging device video output to display with user interface). The transmission time of the video from two compatible C-arms (Siemens Cios Spin, Ziehm Vision RFD 3D) into the Vascular Navigation PAD 2.0 application was measured. The added latency is defined as the time between the image appearing on the monitor cart and its appearance within the Vascular Navigation PAD. From a technical standpoint, however, this latency is measured from the video output of the imaging system to the GUI of the Vascular Navigation PAD application, making it independent of the specific imaging device used.

The test was successfully passed as the Added Latency (AL) is ≤ 250 ms for the values generated for Ziehm Vision RFD 3D, Siemens Cios Spin as well as for both imaging devices combined.

Stress and Load Test:

Tests were conducted to evaluate the behavior of Vascular Navigation PAD 2.0 under realistic and defined boundary conditions. The performance of the Vascular Navigation PAD application was evaluated once under realistic and defined boundary conditions and once under high system load. The acceptance criteria defined for each test scenario are as followed.

Performance under realistic conditions:

- Capture Process: The timespan between the initiation of the Capture process and the start of the capture animation shall be ≤ 1 s.
- Stitching. The timespan between entering stitching and a calculation result (proposal or no match) shall be ≤ 10 s.
- Roadmap/ Overlay display: The timespan between
 - manual initiation of a roadmap
 - selection of an overlay
 - realignment of an overlay and their (updated) display shall be ≤ 10 s.

Stress and Load, Anti-Virus:

The system does not crash and the application is still responsive (reacts to click events without significant waiting periods). There are no significant latencies of touch interaction and/or appearing animations. A normal interaction with the software is possible.

Both tests were successfully passed, as the results satisfy the acceptance criteria.

Level Selection and Overlay Alignment:

These tests were conducted for evaluation of the performance and positional accuracy (alignment) of the Vascular Navigation PAD 2.0 registration algorithm by comparing manually achieved gold standard registrations to the algorithm output.

Level selection performance was tested using images acquired with Siemens Cios Spin, Ziehm Vision RFD 3D and GE OEC Elite CFD, while overlay alignment was tested with data from Siemens Cios Spin and Ziehm Vision RFD 3D.

The semi-automated level selection and overlay alignment algorithm demonstrated a true-positive rate of 95.71 % for suggested overlay alignments. Among these proposed alignments, an average registration accuracy of 1.49 ± 2.51 mm was achieved. The level selection algorithm showed no failures during the test.

(Note: Performance was achieved on cadaveric image data).

This performance is not specific to any particular imaging device, but can only be achieved if the images are acquired in accordance with the following limitations:

- Images should only be acquired from a neutral position (0° orbital and 0° cranial-caudal angulation).
- To ensure that the scale of the patient anatomy is consistent in the acquired images, each of the following must remain constant during image acquisition: Height of the table, Height of the imaging device Zoom level of the imaging device
- Avoid movement of the patient during image acquisition

Modality Detection:

The test objective was to verify the performance of the modality detection algorithm of the Vascular Navigation PAD 2.0 with independent image data consisting of fluoroscopies and angiographies. This algorithm supports the capture workflow during the roadmap creation. Image data was acquired using a Siemens Cios Spin, GE OEC Elite CFD, Philips Zenition and Ziehm Vision RFD 3D imaging device.

The modality detection algorithm has a prediction rate of 99.25 % in determining an image modality, with an accuracy of 100 % for each possible modality. Consequently, no images were misidentified, leading to a fallout rate of 0 %. We can state with 95 % confidence that all acceptance criteria have been successfully met.

Road mapping Accuracy:

The Vascular Navigation PAD 2.0 provides a roadmapping functionality to support endovascular PAD procedures. This test was carried out for the determination of the road mapping accuracy (synonym: overall accuracy) of Vascular Navigation 2.0 in a realistic worst case setup within its intended use. The device achieves a roadmapping accuracy below the acceptance criteria of 5 mm, with 1.57 ± 0.85 mm. Image data was acquired using a Siemens Cios Spin imaging device.

A realistic worst-case parameter set regarding the influence of the parallax effect is identified as follows:

- Image pairs intended for stitching should have an approximate overlap of 20 %, as this is the value recommend to the user. Images without or hardly any overlap would exhibit the greatest error. However, since the device allows the user to utilize images without stitching, such images would not be stitched.
- For registration, the minimum suggested overlap between the live image and the registration image is determined by the use of the algorithm. This is specified as 30 %. If the algorithm does not find a suitable image, the one with the most overlap was selected manually.

Stitching Algorithm:

The test objective was to evaluate the performance of the Vascular Navigation PAD 2.0 stitching algorithm by manually comparing achieved gold standard (GS) stitches to the algorithm output. The gold standard defines, if a human would consider the image pairs matchable. Image data was acquired using a Philips Azurion, Siemens Cios Spin, GE OEC Elite CFD and Ziehm Vision RFD 3D imaging device.

The semi-automated stitching functionality supports the user workflow during endovascular procedures. This implemented algorithm demonstrates true-positive rate of 95 % for suggested stitching alignments. Whereas, the false-positive rate – the incorrect proposal of stitching – is determined to 6.4 %. With a 95 % confidence we can state that the algorithm successfully met it's specified acceptance criteria of a true-positive rate being greater than or equal to 75 % and a false-positive rate less than or equal to 25 %.

5. Conclusion

The comparison of the Subject Device with the predicate device shows that Vascular Navigation PAD has 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.