July 7, 2025

Caranx Medical
℅ Pierrre Berthet-Rayne
CTO of Caranx Medical
12/14 Rue Jean Antoine de Baif
PARIS, 75013
FRANCE

Re: K243884
Trade/Device Name: TAVIPILOT
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic X-ray system
Regulatory Class: Class II
Product Code: OWB, QIH
Dated: June 6, 2025
Received: June 6, 2025

Dear Pierrre Berthet-Rayne:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243884

Device Name
TAVIPILOT

Indications for Use *(Describe)*

TAVIPILOT is an intra-operative software which provides real-time fluoroscopy detection, tracking and marking of the Non-Coronary Cusp and the prosthetic valve, to allow optimal guidance for precise positioning of the prosthetic valve, according to the planning phase, for TAVI/TAVR (transcatheter aortic valve implantation/replacement) procedures. The guidance provided by TAVIPILOT is not intended to substitute the cardiac surgeon's or the interventional cardiologist's judgment and analysis of the patient's condition.

The device is only intended for adults (i.e., 21 years and older).

Contra-indications:
- Patients who have already undergone a TAVI/TAVR or SAVR (surgical aortic valve replacement)
- Patients diagnosed with aortic insufficiency
- Patients for whom the main access for the TAVI/TAVR catheter is not femoral
- Patients who have a non-tricuspid native valve
- Patients who have a permanent Pacemaker implant or temporary Pacemaker within 2 cm from the aortic root, other than the pacing guidewire
- Patients who have thoracic surgical implants
- Patients who are not adults

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)

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K243884 510(k) Summary

510(k) Summary in accordance with 21 CFR 807.92

Submitted by:	Caranx Medical 12/14 Rue Jean Antoine de Baif 75013 Paris France Tel.: +33 982248561 pierre.berthet-rayne@caranx-medical.com
Contact Person:	Dr. Pierre Berthet-Rayne
Position/Title:	CTO
Date of Preparation:	July 7, 2025
Trade Name:	TAVIPILOT
Regulation:	21 CFR 892.1650- Image-intensified fluoroscopic X-Ray system
Product Code(s):	Primary: OWB Secondary: QIH
Class:	Class II

Predicate

Substantial Equivalence to:

K Number	**Model**	**Manufacturer**
Predicate K140138	Philips HeartNavigator Release 2.0	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684 PC Best The Netherlands

Trade Name:	HeartNavigator Release 2.0
Regulation:	21 CFR 892.1650 - Image-intensified fluoroscopic x-ray system.
Product Code(s):	OWB , LLZ
Class:	Class II
Reason for Submission:	New Device

DESCRIPTION OF DEVICE:

TAVIPILOT is an intra-operative software which provides real-time fluoroscopy detection, tracking and marking of the Non-coronary Cusp and the prosthetic valve, to allow optimal guidance for precise positioning of the prosthetic valve, according to the planning phase, for TAVI/TAVR (transcatheter aortic valve implantation/replacement) procedures.

The guidance provided by the TAVIPILOT is not intended to substitute the cardiac surgeon's or the interventional cardiologist's judgment and analysis of the patient's condition.

INTENDED USE:

Indications for Use

TAVIPILOT is an intra-operative software which provides real-time fluoroscopy detection, tracking and marking of the Non-Coronary Cusp and the prosthetic valve, to allow optimal guidance for precise positioning of the prosthetic valve, according to the planning phase, for TAVI/TAVR (transcatheter aortic valve implantation/replacement) procedures. The guidance provided by TAVIPILOT is not intended to substitute the cardiac surgeon's or the interventional cardiologist's judgment and analysis of the patient's condition.

The device is only suitable for adults (i.e., 21 years and older).

Contra-indications:

- Patients who have already undergone a TAVI/TAVR or SAVR (surgical aortic valve replacement)
- Patients diagnosed with aortic insufficiency
- Patients for whom the main access for the TAVI/TAVR catheter is not femoral
- Patients who have a non-tricuspid native valve
- Patients who have a permanent Pacemaker implant or temporary Pacemaker within 2 cm from the aortic root, other than the pacing guidewire
- Patients who have thoracic surgical implants
- Patients who are not adults

Intended Patient Population

TAVIPILOT is suitable for patients with structural heart diseases who are considered appropriate candidates for treatment with a TAVI/TAVR procedure.
This device is only suitable for adults (i.e., 21 years and older).

Intended Users

The user is a clinical specialist who is fully skilled and qualified to perform the TAVI/TAVR procedure and is responsible for sound clinical judgement and for applying the best clinical procedure, such as a cardiac/cardiothoracic surgeon or interventional cardiologist.

Before using TAVIPILOT, users must complete the required training in the safe, intended, and effective use of the device and demonstrate their ability to operate it correctly. Only after receiving certification may a user operate TAVIPILOT. Uncertified users should not have access to the device.

Intended Use Environment

TAVIPILOT is intended to be used in the control room and in the examination room of an interventional suite and/or hybrid operating room. TAVIPILOT integrates in the existing operating room environment, usually containing an examination room (where the patient is), and a control room. The system is connected to an interventional (C-arm) X-ray system.

TECHNOLOGICAL CHARACTERISTICS:

TAVIPILOT utilizes trained AI/ML model to detect, track and mark the Non-coronary Cusp (NCC) and the transcatheter aortic valve (TAV) to guide the operator for precise positioning of the prosthetic valve, according to the planning phase.

AI/ML validation test has shown that the model's ability to accurately detect, track and mark the non-coronary cusp (NCC) with high accuracy, see section Non-Clinical and Performance Testing.

COMPATIBILITY:
TAVIPILOT is compatible with the following medical devices and requirements:

TAV:
- Edwards SAPIEN 3 (20 mm, 23 mm, 26 mm, 29 mm) [P140031]
- Edwards SAPIEN 3 Ultra (20 mm, 23 mm, 26 mm) [P140031]

TAV delivery system:
- Edwards Commander delivery system [P140031]

Pigtail catheter:
- Cordis 534-550S INFINITI ® Diagnostic Catheters Ventricular Pigtail 5F/6F 110 cm [K970854]
- Cordis SR2278 SuperTorque ® Plus Angled Pigtail 5.2F 125 cm [K914007]
- Boston Scientific Impulse 5F 125 cm [K120495]
- Cordis 533-650F SUPER TORQUE Diagnostic Catheters 6F 110 cm [K231015]

Imaging Devices:
FDA cleared X-Ray (Imaging) devices under the following C-arm configurations:
- 3-cusp coplanar view: any C-arm angulation allowing for visualization of the three cusps (non-coronary, right, left) in the same plane, or
- 2-cusp overlap view: any C-arm angulation allowing for visualization of the isolated non-coronary cusp and overlapped right- and left-coronary, and
- avoiding any parallax effect on the TAV, and
- Field of View (FOV) between 160 mm by 160 mm and 300 mm by 300 mm, and
- C-arm acquisition frame rates of 5 to 30 frames per second, and
- Minimum image resolution 512 pixels by 512 pixels, 1:1 aspect ratio

Control Room Computer:
- OS: Windows 11 Pro, 64-bit
- CPU: AMD Ryzen 7 5800H 3.20 GHz, Intel Core i7-11700K 3.10 GHz
- RAM: 16 GB
- GPU: NVIDIA GeForce RTX 3060 (or newer model) with 6 GB of VRAM and compatible with CUDA
- Storage space: 20 GB
- Display resolution of at least 1280 by 1024 pixels
- Frame Grabber (AJA U-Tap HDMI, AJA U-Tap SDI or AV.IO HDMI)
- USB Isolator (CableMax USB Isolator 5000 Vrms Dongle, or any similar device with protection of at least 5000 VDC)

COMPARISON OF TECHNOLOGICAL FEATURES TO PREDICATE DEVICE (SE TABLE):

Product/ Feature	Subject Device (SD): TAVIPILOT	Predicate Device (PD): Philips HeartNavigator 2.0	Substantial Equivalence (SE) and Comments
General information	Product codes: OWB, QIH Classification name: Image-intensified fluoroscopic x-ray system Classification regulation: 21 CFR 892.1650 FDA Clearance: K243884	Product code: OWB, LLZ Classification name: Image-intensified fluoroscopic x-ray system Classification regulation: 21 CFR 892.1650 FDA Clearance: K140138	Similar to PD: Predicate device is legally marketed.

Product/ Feature	Subject Device (SD): TAVIPILOT	Predicate Device (PD): Philips HeartNavigator 2.0	Substantial Equivalence (SE) and Comments
Intended Use (IU) including Indications for Use (IFU)	TAVIPILOT is an intra-operative software which provides real-time fluoroscopy detection, tracking and marking of the Non-Coronary Cusp and the prosthetic valve, to allow optimal guidance for precise positioning of the prosthetic valve, according to the planning phase, for TAVI/TAVR (transcatheter aortic valve implantation/replacement) procedures. The guidance provided by TAVIPILOT is not intended to substitute the cardiac surgeon's or the interventional cardiologist's judgment and analysis of the patient's condition. The device is only intended for adults (i.e., 21 years and older). Contra-indications: - Patients who have already undergone a TAVI/TAVR or SAVR (surgical aortic valve replacement) - Patients diagnosed with aortic insufficiency - Patients for whom the main access for the TAVI/TAVR catheter is not femoral - Patients who have a non-tricuspid native valve - Patients who have a permanent Pacemaker implant or temporary Pacemaker within 2 cm from the aortic root, other than the pacing guidewire - Patients who have thoracic surgical implants - Patients who are not adults	HeartNavigator is a tool to assist the user with the treatment of structural heart disease using minimal invasive interventional techniques. In addition to the conventional live fluoroscopy it provides the user with tools to plan and guide the procedure using 3D image data.	Similar to PD: SD does not assist the user with procedure planning. SD provides support for a specific structural heart disease treatment procedure, namely TAVI/TAVR.
Device Description	The TAVIPILOT software tool is intended to be used in combination with FDA cleared X-ray systems to assist cardiac surgeons and interventional cardiologists with the treatment of structural heart diseases using minimal invasive interventional techniques for which TAVI/TAVR is indicated.	The HeartNavigator software tool is intended to be used in combination with the primary predicate device Allura X-ray system (K130638) to assist cardiac surgeons and interventional cardiologists with the treatment of structural heart diseases using minimal invasive interventional techniques.	Similar to PD: Both devices are intended to assist cardiac surgeons and interventional cardiologists with the treatment of structural heart diseases using FDA cleared X-Ray C-arm systems and minimal invasive interventional techniques. SD provides support for a specific structural heart disease treatment procedure, namely TAVI/TAVR.
	In addition to conventional live fluoroscopy TAVIPILOT provides the user with tools to guide the procedure using a 2D projection of the aortic root-related landmarks and transcatheter aortic valve overlayed on the 2D X-ray image data from the FDA cleared X-ray systems	In addition to conventional live fluoroscopy HeartNavigator provides the user with tools to plan (by use of previously acquired DICOM cardiac CT patient data) and guide the procedure using a 2D projection of the aortic root-related landmarks obtained during planning, on X-ray image data from the Allura X-ray system.	Similar to PD: Both PD and SD use 2D overlay on the fluoroscopic image for guidance. SD does not assist the user with procedure planning in the planning phase

Product/ Feature	Subject Device (SD): TAVIPILOT	Predicate Device (PD): Philips HeartNavigator 2.0	Substantial Equivalence (SE) and Comments
	During Live phase the SD offers anatomical detection and tracking of the aortic root-related landmarks and transcatheter aortic valve which is overlayed in 2D on the 2D fluoroscopy x-ray image data using trained AI/ML model.	During live phase the PD converts the 3D CT-data to a 2D projection of the aortic root-related landmarks, which is overlayed on the 2D fluoroscopy x-ray image.	Different in technology: Both PD and SD offer anatomical detection, tracking and marking of the aortic root. Both PD and SD use 2D overlay on the fluoroscopic image for guidance. SD uses a trained AI/ML model
	TAVIPILOT does not change or influence the TAVI procedure	HeartNavigator 2.0 does not change or influence the TAVI procedure	Same as PD
Patients, Users & Environment	**Patient Population:** TAVIPILOT is suitable for patients with structural heart diseases who are considered appropriate for treatment with a TAVI/TAVR procedure.	**Patient Population:** HeartNavigator 2.0 is suitable for patients with structural heart diseases that have a medical condition for which the treatment with minimal invasive interventional techniques using fluoroscopy is considered suitable.	Same as PD SD is specifically suitable for patients with structural heart diseases for which TAVI/TAVR is indicated.
	Intended users: The user is a clinical specialist who is fully skilled and qualified to perform the TAVI/TAVR procedure and is responsible for sound clinical judgement and for applying the best clinical procedure	**Intended users:** The user is a clinical specialist who is fully skilled and qualified to perform the structural heart disease procedure and is responsible for sound clinical judgement and for applying the best clinical procedure.	Same as PD SD's intended users are skilled and qualified to perform a specific structural heart disease procedure, namely TAVI/TAVR.
	General safety and effectiveness: To facilitate safe and efficacious operation of the system by a trained healthcare professional, instructions for use are provided as part of the labelling, as well as training at system handover.	**General safety and effectiveness:** To facilitate safe and efficacious operation of the system by a trained healthcare professional, instructions for use are provided as part of the labelling, as well as training at system handover.	Same as PD
	Clinical environment: TAVIPILOT is intended to be used in the control room and in the examination room of an interventional suite and/or hybrid operating room.	**Clinical environment:** HeartNavigator is intended to be used in the control room and in the examination room of an interventional suite and/or hybrid operating room.	Same as PD
	Computer (PC) environment • Windows operating system • Video capture for receiving C-arm X-ray fluoroscopic images • Output to LDM (Large Display Monitor)	**Computer (PC) environment** • Windows operating system • Video capture for receiving C-arm X-ray fluoroscopic images • Output to LDM (Large Display Monitor)	Same as PD
Principle of Operation and Technology	The main operating principle of TAVIPLIOT consists of the following SW workflow: 1. Preparing for Live task 2. Live Task	The main operating principle of HeartNavigator consists of the following SW workflow: 1. Planning segmentation task 2. Planning measurement task 3. Planning viewing task 4. Planning registration task 5. Preparing for Live task 6. Live Task	Similar to PD: The intended use of the SD is not to assists the user with TAVI procedure planning, therefore steps 1-4 of the PD steps are not relevant for the SD.

Product/ Feature	Subject Device (SD): TAVIPILOT	Predicate Device (PD): Philips HeartNavigator 2.0	Substantial Equivalence (SE) and Comments
TAVIPILOT SW Workflow – Preparing for Live Task	Valve type, valve size and positioning are selected by the user in the preparing for live tasks	Valve type, size and positioning are selected by the user in the preparing for live tasks.	Same as PD Both SD and PD requires valve type, size and positioning input by the user.
TAVIPILOT SW Workflow – Live Task	**Live task – reception of fluoroscopic data** Reception of live fluoroscopic stream from an FDA-cleared X-Ray system	**Live task – reception of fluoroscopic data** Reception of live fluoroscopic stream from the Allura X-ray system (K130638)	Similar to PD Both devices receives live fluoroscopic images from a cleared X-ray system
	Live task – displaying raw fluoroscopic data During Live Task the TAVIPILOT is displayed in addition to the original raw fluoroscopic data (image), on the large monitor as a separate fluoroscopic image with the overlayed guidance information	**Live task – displaying raw fluoroscopic data** During Live Task the HeartNavigator 2.0 is displayed in addition to the original raw fluoroscopic data (image), on the large monitor as a separate fluoroscopic image with the overlayed guidance information	Same as PD: Both SD and PD keep an original raw fluoroscopic image flow and provide their guidance on a separate flow
	Live tasks - Aortic root-related landmarks: Upon detection, the aortic root-related landmarks are displayed to the user by overlaying a 2D landmark on the 2D live x-ray images.	**Live tasks - Aortic root-related landmarks:** Upon detection, the aortic root-related landmarks are displayed to the user by overlaying a 2D landmark (NCC, LCC and RCC) on the live 2D x-ray images.	Similar to PD: Both systems display 2D landmarks on the live 2D fluoroscopic stream for marking of the NCC. SD only displays NCC as a dot, PD displays NCC, LCC and RCC as a circle
	Live tasks – Transcatheter Aortic Valve (TAV): Upon detection, the TAV is displayed to the user by overlaying a 2D on the live 2D x-ray images.	**Live tasks – Transcatheter Aortic Valve (TAV):** The TAV is displayed to the user by overlaying a 2D landmark (2D valve overlay) on the live 2D x-ray images.	Similar to PD: Both systems displays 2D landmarks on the live 2D fluoroscopic stream for marking of the TAV. SD displays TAV as line overlay, PD displays TAV as multiple line overlay

In the SE table above, we have identified a difference in technological characteristics, which is:

- the PD uses previously acquired CT data for detection and overlaying of 2D aortic root-related landmark (NCC) and 2D aortic transcatheter valve landmark (TAV) on 2D live fluoroscopy

whereas

- the SD uses AI/ML-models for detection and overlaying of 2D aortic root-related landmark (NCC) and 2D aortic transcatheter landmark (TAV) on 2D live fluoroscopy

This difference in technological characteristic was evaluated through non-clinical and performance testing.

NON-CLINICAL AND PERFORMANCE TESTING:

In addition to the verification testing conducted as part of the software lifecycle development process, non-clinical and performance testing was carried out to demonstrate TAVIPILOT substantial equivalence.

Below is a summary of these tests and results:

FDA cleared C-arm X-ray device interoperability testing:

TAVIPILOT was validated for compatibility and interoperability with FDA cleared C-arm X-ray devices (using data from GE, Philips, and Siemens devices).

TAVIPILOT was deployed in different TAVI centers, each using different FDA cleared C-arm X-ray devices.

The validation confirmed that TAVIPILOT is compatible and can interoperate with any FDA cleared GE, Philips, and Siemens C-arm X-ray device that meets the requirements listed in the "Compatibility" section.

NCC and TAV detection, tracking and marking validation testing:
TAVIPILOT was validated for its accuracy in detecting, tracking and marking of the NCC and the TAV.

The validation included a representative and statistically supported number of patients, representative of both EU and US TAVI populations, including gender and ethnicity considerations.
The validation compared TAVIPILOTs detecting, tracking and marking accuracy to ground truth. Ground truth was performed by board certified experts with substantial experience with relevant clinical tasks, thus ensuring quality annotations.

The validation demonstrated that TAVIPILOT has a high accuracy in detecting, tracking and marking of the NCC and the TAV. The NCC was detected, tracked and marked ≤ 2 mm in 100% of all patients being tested with statistical significance. The TAV was detected, tracked and marked ≤ 1 mm in 100% of all patients being tested with statistical significance. The accuracy was obtained in both contrasted and non-contrasted images.

Comparison to Predicate Device testing:
TAVIPILOT was validated for comparison to the Predicate Device.
The validation included a representative and statistically supported number of patients. The validation compared TAVIPILOTs and the Predicate Device detecting, tracking and marking accuracy to ground truth. Ground truth was performed by board certified experts with substantial experience with relevant clinical tasks, thus ensuring quality annotations.

The validation demonstrated that TAVIPILOT has equivalent or better detection, tracking, and marking of the NCC compared to the predicate device in all patients. The accuracy was obtained in both contrasted and non-contrasted images.

Summary:
TAVIPILOT was successfully validated for compatibility and interoperability with FDA cleared C-arm X-ray devices, for its accuracy in detecting, tracking and marking of the NCC and the TAV and for comparison to the Predicate Device and supports our claim of substantial equivalence to the predicate device.

APPLICATION OF STANDARDS:

TAVIPILOT software was developed and documented in accordance with FDA guidelines for SW development, verification and validation. The software lifecycle process was evaluated to meet:

- Medical device software lifecycle process per IEC 62304:2006+A1:2015 as per internal SW development QMS-procedure under ISO13485:2016, and
- Device software was verified to requirements and validated to meet the specified intended use.

TAVIPILOT was evaluated for usability and met acceptance criteria for performance after testing.
TAVIPILOT was tested to current applicable standards for medical device. The following standards were applied for development and compliance testing:

- IEC 62366-1:2015+AMD1:2020 Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1 – FDA 5-129
- IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)] – FDA 13-79

The device met acceptance criteria for compliance to the standards.

Safety and security Risk management, risk and hazard analysis were performed to the following standards:

- ISO14971:2029 Medical devices - Applications of risk management to medical devices – FDA 5-125
- CR34971:2022 Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning – FDA 13-124
- TIR57:2016 Principles for medical device security - Risk management.

The device met risk management criteria for acceptability of residual risks.

In summary, TAVIPILOT met acceptance criteria for conformance to applicable standards and performance. Residual risks met criteria for acceptability for the intended use. Cybersecurity documentation was provided as described in FDA guidance document *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*.

CONCLUSION:

Therefore, we believe that the difference in technological characteristic does not raise other questions regarding safety and effectiveness and that TAVIPILOT is substantially equivalent to the predicate device.