



February 11, 2026

SAVFE Co. Ltd.  
% Hsiao Man Hsu  
Project Manager  
2F., No.89, Qiaohe Rd.  
Zhonghe Dist.,  
New Taipei City, 235030  
TAIWAN

Re: K251992

Trade/Device Name: ArmSure Fluoroscopic Positioning System  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image-Intensified Fluoroscopic X-Ray System  
Regulatory Class: Class II  
Product Code: OWB, LLZ, JAA  
Dated: January 12, 2026  
Received: January 12, 2026

Dear Hsiao Man Hsu:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A large, light blue watermark of the letters "FDA" is visible in the background. Overlaid on this watermark is the name "Lu Jiang" written in a black, cursive script.

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)  
K251992

Device Name  
ArmSure Fluoroscopic Positioning System

### Indications for Use (Describe)

The ArmSure Fluoroscopic Positioning System is a software-enabled manual Assist Arm intended for use with fluoroscopic systems to assist in the visualization of the spatial relationship of attached compatible surgical instruments and interventional accessories on X-ray images, and to maintain the corresponding spatial position to hold the attached instrument or accessory.

The ArmSure system is intended to be used by trained healthcare professionals in a clinical environment, and is indicated for use during fluoroscopically-guided procedures involving the spine and long bones in patients whose anatomical size is suitable for the compatible instruments and the host fluoroscopic system.

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

Prescription Use (Part 21 CFR 801 Subpart D)

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

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) Summary – K251992

### I. Submitter

<b>Company Name</b> SAVFE Co. Ltd.
<b>Address</b> 2F., No.89, Qiaohe Rd., Zhonghe Dist., New Taipei City 235030, Taiwan
<b>Contact Person (Primary)</b> Hsiao Man (Ethel) Hsu +886-905-221-800 ethelhsu@savfetechnology.com
<b>Date Preparation</b> 2026/02/11

### II. Device

<b>Device Name</b> ArmSure Fluoroscopic Positioning System
<b>Device Common Name</b> Interventional Fluoroscopic X-ray System
<b>Device Classification</b> Class II
<b>Regulation Number</b> 892.1650 - Image-intensified fluoroscopic X-ray system
<b>Product Code</b> OWB - interventional fluoroscopic X-ray system
<b>Associated Product Code</b> LLZ, JAA

### III. Predicate Devices

Device Name	TrackX	TrackX v.2.0
<b>Manufacturer</b>	Track X Technology, LLC	Track X Technology, LLC
<b>510(k) Number</b>	K173736	K200360
<b>Regulation Number</b>	892.1650	892.1650
<b>Product Code</b>	OWB	OWB
<b>Subsequent Product Codes</b>	LLZ, JAA	LLZ, JAA
<b>Reference Devices</b>	No reference devices were used in this submission	

#### **IV. Indications for Use**

The ArmSure Fluoroscopic Positioning System is a software-enabled manual Assist Arm intended for use with fluoroscopic systems to assist in the visualization of the spatial relationship of attached compatible surgical instruments and interventional accessories on X-ray images, and to maintain the corresponding spatial position to hold the attached instrument or accessory.

The ArmSure system is intended to be used by trained healthcare professionals in a clinical environment, and is indicated for use during fluoroscopically-guided procedures involving the spine and long bones in patients whose anatomical size is suitable for the compatible instruments and the host fluoroscopic system.

#### **V. Device Description**

The ArmSure Fluoroscopic Positioning System combines a software application with an Assist Arm to provide real-time visualization of surgical instrument locations within X-ray images. The visualization is derived from data transmitted by the Assist Arm to the ArmSure software, which performs calculations based on image coordination to superimpose the instrument's position onto the fluoroscopic X-ray images.

The Assist Arm is a manual, non-actuated device designed to be operated by the surgeon at the patient's side. The surgeon manually manipulates the Assist Arm in response to the interactive feedback displayed on the external screen, enabling precise instrument positioning through this real-time interface.

#### **VI. Regulatory Conformity**

ArmSure Fluoroscopic Positioning System is designed per recommendations provided in the following FDA guidance documents:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Off-The-Shelf Software Use in Medical Devices
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices

**VII. Comparison of Technological Characteristics**

Description	Subject Device: SAVFE Co., Ltd.	Predicate Device I: K173736	Predicate Device II: K200360	Comparison
<p><b>Indications for use</b></p>	<p>The ArmSure Fluoroscopic Positioning System is a software-enabled manual Assist Arm intended for use with fluoroscopic systems to assist in the visualization of the spatial relationship of attached compatible surgical instruments and interventional accessories on X-ray images, and to maintain the corresponding spatial position to hold the attached instrument or accessory.</p> <p>The ArmSure system is intended to be used by trained healthcare professionals in a clinical environment, and is indicated for use during</p>	<p>Indicated for use in any application where a fluoroscope is incorporated to aid in the diagnosis and treatment of disease</p>	<p>Indicated for use in any application where a fluoroscope is incorporated to aid in the diagnosis and treatment of disease</p>	<p>Equivalent</p>

	fluoroscopically-guided procedures involving the spine and long bones in patients whose anatomical size is suitable for the compatible instruments and the host fluoroscopic system.			
<b>Compatible Hardware Platforms</b>	CPU: Intel i7-9700E GPU: NVIDIA T1000 RAM: 32G SSD: 1T Frame Grabber: DVP-7011HE-1 Operating System: Windows 11	Any computer that meets the following minimum specifications: CPU: Intel i5 GPU: NVIDIA 760 RAM: 8 GB HDD: 256 GB Frame Grabber: Aver Media H339 or Elgato Operating System: Windows 10	Any computer that meets the following minimum specifications: CPU: Intel i5 GPU: NVIDIA 760 RAM: 8 GB HDD: 256 GB Frame Grabber: Aver Media H339, Elgato or Accustream Operating System: Windows 10	Minor Difference
<b>Software is run on a stand-alone computer and monitor</b>	Yes	Yes	Yes	Equivalent
<b>Device is passive and doesn't control the fluoroscope</b>	Yes	Yes	Yes	Equivalent
<b>For use during procedures</b>	Yes	Yes	Yes	Equivalent

<b>that involve fluoroscopy</b>				
<b>Provides visual cues which help guide the user in positioning the instrument back to where it was when a prior x-ray image of it was taken.</b>	Yes	Yes	Yes	Equivalent
<b>Requires a tracking system when tracking is being used.</b>	Yes	Yes	Yes	Equivalent. Unlike typical predicate devices that utilize optical or electromagnetic tracking, the ArmSure System utilizes a mechanical tracking method via the Assist Arm M7. This approach ensures reliable tracking performance without common environmental interferences.
<b>Requires a tracker to interface with the tracking system.</b>	Yes	Yes	Yes	Equivalent
<b>Requires a sterile tracker attached to the instrument</b>	Yes	Yes (TrackX Snaps – identical to the NuX Snaps used with	Yes	Equivalent

<b>in order to track the location of the tip of the surgical instrument</b>		predicate)		
<b>Tracking system type</b>	Positioning arm system	Electromagnetic or optical tracking system	Electromagnetic or optical tracking system	Minor Difference
<b>System Accuracy Specification</b>	99.7% C.I. < 1.5mm	N/A (only “close enough” in 510(k) summary)	Mean < 2mm	Improvement

## **VIII. Performance Testing**

The following performance data were provided in support of the substantial equivalence determination.

### **Biocompatibility**

Based on ISO 10993 standards, the Instrument Guide is categorized as a surface-contacting device with limited exposure to skin and tissue. Comprehensive testing, including cytotoxicity, sensitization, and irritation assessments, confirms that the device elicited no adverse biological responses. Therefore, the biocompatibility of the Instrument Guide is verified, ensuring it is safe for its intended clinical use in surgical procedures.

### **Sterilization**

The ArmSure system consists of reusable and single-use components. The End-Effector Adapter and Registration Device are provided non-sterile and require cleaning and sterilization before use. Single-use accessories, such as the Sterile Drape and Instrument Guide, are sterilized via Ethylene Oxide (EO) according to ISO 11135 (SAL  $10^{-6}$ ). These components have undergone ASTM-standard packaging validation—including environmental, transit, and accelerated aging tests—to ensure sterile integrity throughout their shelf life.

### **Electrical Safety and Electromagnetic Compatibility**

The ArmSure system was tested and found to be in full compliance with IEC 60601-1 for basic electrical safety and IEC 60601-1-2 for electromagnetic compatibility. As an integrated system, the mechanical arm and control unit were subjected to rigorous electrical safety tests, with all results falling within the specified limits. EMC testing, which included assessments of conducted/radiated emissions and immunity, confirmed that the system is suitable for use in a professional healthcare facility environment. The results demonstrate that the device is not expected to cause harmful interference to other co-located equipment (such as ECG monitors or image intensifiers) and can tolerate expected levels of ambient electromagnetic disturbances.

### **Software Verification and Validation Testing**

Software verification and validation (V&V) testing was conducted for the ArmSure system. The accompanying documentation was prepared in accordance with the recommendations in the FDA's guidance document, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions." Based on a risk analysis of the software's functions in the context of the device's intended use, the software documentation level for this device has been determined to be "Basic" documentation level.

## **Bench Testing**

The ArmSure Fluoroscopic Positioning System underwent a series of non-clinical performance bench tests to verify that the device performs according to its design specifications and is substantially equivalent to the predicate devices.

- Verification of 3D repeatability and positional accuracy was conducted with reference to ISO 9283 and ASTM F2554. All test results demonstrated that the system's accuracy surpassed the pre-defined design specification of  $\leq 1.0$  mm for positioning error.
- Performance was evaluated using anatomical phantoms to simulate surgical pathways involving rigid structures. The study incorporated simulations of clinical worst-case scenarios, including extreme imaging conditions. Statistical analysis confirmed that for all tests, the upper bound of the 99.7% confidence interval for positional accuracy remained below the 1.5 mm acceptance criterion. The validation demonstrates that the system maintains robust and stable guidance accuracy even under challenging clinical imaging conditions.
- Usability validation was performed in accordance with IEC 62366-1:2015/AMD 1:2020 and the FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices" (2016). The results showed that clinical users achieved a 100% success rate across five identified critical tasks. No use errors or safety-related incidents were observed, confirming that intended users can operate the device safely and effectively within the clinical environment.

## **IX. Conclusion**

The ArmSure Fluoroscopic Positioning System shares similar intended use and similar technological characteristics as the predicate devices, TrackX (K173736 and K200360). While the subject device utilizes a mechanical tracking method via the Assist Arm, this difference does not raise new questions of safety or effectiveness.

Non-clinical performance testing and usability validation demonstrate that the system achieves superior positional accuracy and can be operated safely and effectively by the intended users. These results, combined with the device's design characteristics, ensure that the system performs as safely and effectively as the predicate, as intended.

In summary, the information provided in this premarket notification demonstrates that the ArmSure Fluoroscopic Positioning System is substantially equivalent to the legally marketed predicate devices.