October 17, 2025

X9, Inc.
c/o Melissa Viotti
Quality and Regulatory Consultant
10 Research Parkway, Ste 350
Wallingford, Connecticut 06492

Re: K251673
Trade/Device Name: X9 Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: SGH, IYO, ITX, QIH
Dated: September 15, 2025
Received: September 17, 2025

Dear Melissa Viotti:

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,

Gema Gonzalez -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
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)*
K251673

Device Name
X9 Ultrasound System

Indications for Use *(Describe)*
The X9 Ultrasound System is intended for ultrasound imaging of validated vascular accesses for hemodialysis during the preliminary stage of a cannulation procedure, prior to inserting the needle. The device is intended to be used by qualified healthcare professionals in a medical setting. The device is not intended to be used to diagnose the position of the vascular access without confirming position per standard of care. The X9 Ultrasound System is not for use in pediatric patients.

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

1. Contact Details

Applicant Name: X9, Inc.
Applicant Address: 10 Research Parkway, STE 350, Wallingford, CT 06492
Applicant Contact Telephone: (650) 472-0307
Applicant Contact: Earl "Eb" Bright
Applicant Contact Email: ebright@x9med.com
Date Summary Prepared: October 17, 2025

2. Device Name

Device Trade Name: X9 Ultrasound System
Common Name: Ultrasonic System
Classification Name: Ultrasonic pulsed echo imaging system
Regulation Number: 892.1560
Product Code: SGH, IYO
Classification Name: Diagnostic ultrasonic transducer
Regulation Number: 892.1570
Product Code: ITX
Classification Name: Medical image management and processing system
Regulation Number: 892.2050
Product Code: QIH

3. Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name	Product Code
K211193	BD Prevue™ II Peripheral Vascular Access System	IYO – ITX – LLZ

4. Device Description Summary

The X9 Ultrasound System is intended for guidance in accessing arteriovenous fistulas and grafts (AVF/G). The X9 Ultrasound System consists of a Handpiece and Software. The Handpiece is a handheld device with an ultrasound transducer and is attached via a cable to a user-supplied Computer. The Handpiece is covered by a compatible probe cover and is placed on the patient's limb and positioned (translated/rotated) by the user to align with the AVF/G. The Handpiece contains a physical button for the user to activate/deactivate the system and an alignment marking to assist the user with positioning the Handpiece over the vessel. The software, which runs on a standard operating system platform installed on the Computer, provides the Graphical User Interface (GUI). The GUI will indicate when the Handpiece is aligned with the AVF/G. The information given from the system is intended to guide the user so that they can efficiently proceed with the standard of care assessment prior to cannulation.

5. Intended Use / Indications for Use

The X9 Ultrasound System is intended for ultrasound imaging of validated vascular accesses for hemodialysis during the preliminary stage of a cannulation procedure, prior to inserting the needle. The device is intended to be used by qualified healthcare professionals in a medical setting. The device is not intended to be used to diagnose the position of the vascular access without confirming position per standard of care. The X9 Ultrasound System is not for use in pediatric patients.

6. Indications for Use Comparison

The BD Prevue™ II Peripheral Vascular Access System is intended for diagnostic ultrasound imaging of the human body performed by appropriately trained healthcare professionals in a medical setting. Specific clinical applications include:

• Pediatric

• Peripheral Vessel and Vascular Access

Typical examinations performed using the BD Prevue™ II System include:

Imaging Applications	**Exam Type (Adult and Pediatric)**
Vascular	Assessment of vessels in the extremities and neck leading to or coming from the heart, superficial veins in the arms and legs, and vessel mapping. Assessment of superficial thoracic vessels.
Vascular Access	Guidance for PICC, CVC, dialysis catheter, port, PIV, midline, arterial line placement, access to fistula and grafts, and general vein and artery access

The X9 Ultrasound System's indications for use are encompassed by the broader indications of the predicate device. The X9 Ultrasound System is not for use in pediatric patients.

7. Technological Comparison

A comparison of the X9 Ultrasound System (subject device) to the BD Prevue™ II Peripheral Vascular Access System (predicate device) demonstrated that any differences between the subject device and predicate device do not constitute a new intended use, and any differences in technological characteristics do not raise new questions of safety and effectiveness. Both subject and predicate devices are intended for use in a hospital/clinic medical setting by a trained clinician. Both systems consist of B-mode imaging ultrasound probes and utilize software analysis during use.

8. Clinical Performance Data

No clinical testing was conducted in support of the X9 Ultrasound System, as the intended use, indications, and technology are equivalent to those of the predicate device. The non-clinical

testing summarized in this submission supports the substantial equivalence of this device to the predicate with respect to safety and effectiveness.

9. Non-Clinical Test Summary

X9, Inc. has conducted extensive verification and validation testing of the X9 Ultrasound System. The subject device was tested to ensure that it can provide all the capabilities necessary to operate safely and effectively. Acceptance criteria have been established to ensure that the subject device performs in a manner that is substantially equivalent to the cited predicate device. Testing was conducted to verify the safety and performance requirements of the subject device, and the test results support substantial equivalence to the predicate device. The following nonclinical tests were performed on the subject X9 Ultrasound System for a determination of substantial equivalence.

- Acoustic Safety Testing
- Electrical Safety Testing
- Electromagnetic Compatibility Testing
- Mechanical and Thermal Safety Testing
- Software Verification Testing
- Cybersecurity Testing
- Bench Performance Testing
- User Needs Testing
- Ship Testing
- Machine Learning Validation Testing

A Machine Learning Model Validation was performed to confirm that the ML model correctly determined if an access vessel was visible and if the average lateral error between the ML Model and the access vessel True Location was acceptable. For the ML Model Validation, the X9 Ultrasound System was used to collect 378 B-mode ultrasound images on 63 participants known to have an arteriovenous fistula or graft (AVF/G). Participants had their access vessel scanned using the ultrasound handpiece and a laptop running an application capable of saving scanned data. From each participant scan dataset, images at three timepoints were selected in accordance with the approved protocol and analyzed by three independent sonographers to establish ground truth. The training dataset was collected at dialysis clinics not included in the ML model validation and was used exclusively for model training. Separate test datasets were reserved for performance validation against expert-annotated ground truth. ML model validation clinic locations were selected to obtain a sample of participants and included 31 females, 32 males, 34 Black/African American, 27 White, 1 Asian, 1 Unknown/Not Reported, 4 Hispanic or Latino, and 59 Not Hispanic or Latino. The participant age ranged from 18 to 75+ years old. Fifteen (15) participants presented with AV Grafts and 48 with AV Fistulas.

The reviewers used their clinical expertise to determine if an access vessel was visible in each image or not. A subset of images called the “Access Present Subset” was created, containing all images where the majority of independent reviewers determined that an access vessel was

present in the image. The Access Presence Sensitivity percentage was calculated from the number of images where the ML Model determined that an access vessel is present divided by the total number of images in the subset. The "true location" of the access vessel was established by calculating the average of the locations annotated by each of the independent reviewers. The lateral error of the ML Model was calculated as the difference between the True Location of the access vessel and the ML model lateral access vessel location.

The Machine Learning Model (and therefore the X9 Ultrasound System) met the ML Model Validation acceptance criteria for the primary analyses. The calculated Access Presence Sensitivity was 94.5%, which exceeded the acceptance criteria of greater than or equal to 75%. The average lateral error between the ML Model and the access vessel True Location was 0.492 mm, which met the acceptance criterion of 3mm maximum. The average Dice Similarity Coefficient (DSC) across all reviewers was 81.3%, which meets the acceptance criterion of 75% minimum.

10. Conclusion

The subject device met all design specifications and non-clinical testing provided support of the substantial equivalence determination.