August 3, 2026

ACIST Medical Systems, Inc.
% Prithul Bom, CEO
Regulatory Technology Services
1000 Westgate Drive, Suite 510k
Saint Paul, MN 55114

Re: K262115
Trade/Device Name: VueJect® Ultrasound Enhancing Agent Delivery System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: IZQ
Dated: June 23, 2026
Received: June 23, 2026

Dear Prithul Bom:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

SHRUTI N. MISTRY -S

Shruti Mistry
Assistant Director
DHT3C: Division of Drug Delivery and General Hospital Devices, and Human Factors
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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)*
K262115

Device Name
VueJect® Ultrasound Enhancing Agent Delivery System

Indications for Use *(Describe)*
The VueJect Ultrasound Enhancing Agent Delivery System is intended for controlled intravenous delivery of ultrasound contrast agents in patients undergoing diagnostic ultrasound procedures. For a list of compatible contrast agents, consult the User Guide for the VueJect Ultrasound Enhancing Agent Delivery 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.

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K262115 510(k) Summary

Per 21 CFR 807.92

1. Submitter

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Date Prepared: August 3, 2026

2. Device

Name of Device: VueJect® Ultrasound Enhancing Agent Delivery System
Common or Usual Name: Automatic Contrast Medium Injector
Classification Name: Angiographic injector and syringe (21 CFR 870.1650)
Regulatory Class: II
Product Code: IZQ

3. Predicate and Reference Devices

	Predicate Device	Reference Device
Name of Device	Empower CT and Empower CTA Injection Systems	Single-use Sterile High-pressure Angiographic Syringe and Accessories
Common Name	Automatic Contrast Medium Injector	Angiographic syringe and accessories
510(k) Number	K071378	K241109
Classification Name	Computed tomography x-ray system (21 CFR 892.1750) Impedance plethysmograph (21 CFR 870.2770) Angiographic injector and syringe (21 CFR 870.1650)	Angiographic injector and syringe (21 CFR 870.1650)
Classification	Class II	Class II
Product Code	JAK, DSB, IZQ	DXT

The predicate and reference devices have not been subject to a design-related recall.

4. Device Description

The VueJect® Ultrasound Enhancing Agent Delivery System (VueJect) is a syringe-based automatic contrast injection system intended for the vascular administration of contrast. VueJect consists of an electronic injector unit and tethered remote control, a sterile single-use disposable syringe and tubing, and two optional accessories, the ultrasound remote dock and the power supply clamp.

The single-use disposable syringe and tubing are packaged in a pouch constructed of Tyvek 2FS and Nylon film and sealed. Twenty-five pouches are packaged in a carton with an insert containing directions to access the electronic instructions for use (e-IFU insert) and are sterilized by gamma irradiation. The single-use disposables have indirect contact with blood for a prolonged duration. There are two available configurations of disposable kit:

- V90 kit, containing one 20 mL syringe and 90 cm tubing
- V150 kit, containing one 20 mL syringe and 150 cm tubing

VueJect includes a motor-driven mechanism that gently rotates the syringe back and forth to agitate the fluid inside to maintain homogeneous suspension of ultrasound microsphere contrast. VueJect can administer contrast in either a "bolus" or "infusion" mode. In bolus mode, contrast is administered until a set volume is delivered (or the bolus is stopped early by the user), while in infusion mode contrast is administered at a set flow rate until it is stopped by the user or the syringe is empty. The user may adjust the flow rate while the infusion progresses.

The VueJect system is intended to be used with the following components, which are not supplied with the system:

- Patient access device (also used for hand injections currently)
- Stopcock (optional, placed between end of VueJect tubing and patient access, also used for hand injections currently)
- Ultrasound enhancing contrast agents

5. Indications for Use

The VueJect Ultrasound Enhancing Agent Delivery System is intended for controlled intravenous delivery of ultrasound contrast agents in patients undergoing diagnostic ultrasound procedures. For a list of compatible contrast agents, consult the User Guide for the VueJect Ultrasound Enhancing Agent Delivery System.

6. Comparison with the Predicate Device

The VueJect Ultrasound Enhancing Agent Delivery System is substantially equivalent to the predicate device, Empower CT and Empower CTA Injection Systems, K071378. In addition, the test methods utilized for the VueJect disposables are similar to the reference device, Single-use Sterile High-pressure Angiographic Syringe and Accessories, K241109, which are compatible with the Empower CT and Empower CTA Injection Systems.

Comparative Analysis - VueJect Ultrasound Enhancing Agent Delivery System Compared to Predicate and Reference Devices

Device Property	VueJect Ultrasound Enhancing Agent Delivery System (K262115) (subject device)	Empower CT® and Empower CTA Injection Systems (K071378) (predicate device)	Single-use Sterile High-pressure Angiographic Syringes and Accessories (K241109) (Reference Device)	Comparison
Intended use	For controlled intravenous delivery of contrast media	For controlled intravenous delivery of contrast media	For the injection of contrast media or saline	Same
Indication for use	The VueJect Ultrasound Enhancing Agent Delivery System is intended for controlled intravenous delivery of ultrasound contrast agents in patients undergoing diagnostic ultrasound procedures. For a list of compatible contrast agents, consult the User Guide for the VueJect Ultrasound Enhancing Agent Delivery System.	Administration of contrast and flushing media in conjunction with computed tomography (CT) scanning of the body with an optional interface to a CT scanner	For the injection of contrast media or saline, they shall be used with U.S. legally marketed angiographic injectors	Different
Design	Single-use syringe, software controlled, venous	Single-use syringe, software controlled, venous	N/A	Same as predicate

Device Property	VueJect Ultrasound Enhancing Agent Delivery System (K262115) (subject device)	Empower CT® and Empower CTA Injection Systems (K071378) (predicate device)	Single-use Sterile High-pressure Angiographic Syringes and Accessories (K241109) (Reference Device)	Comparison
	side, low pressure injector	side, low pressure injector		
Anatomical sites	Inject contrast into a peripheral vein	Inject contrast and flushing media into a peripheral vein	N/A	Same as predicate
Associated contrast type	Ultrasound (microsphere) contrast	Radiopaque contrast	N/A	Different. See note 1 below table.
User-determined flow rate	Yes	Yes	N/A	Same as predicate
Flow rate range	0.5 to 4.0 mL/min in 0.1 mL increments (for 90 cm kit) 1.0 – 10.0 mL/min in 0.1 mL/min increments (for 150 cm kit)	6 to 600 mL/min	N/A	Different. See note 2 below table.
Delivery volume	0.5-20 mL	1 to 200 mL	200 mL syringe	Different. See note 2 below table.
Max pressure	600 mbar (11.6 psi)	300 psi	N/A	Different. See note 2 below table.
Pressure limiting	Yes	Yes	N/A	Same as predicate
Mechanical Agitation of Contrast Agent	Yes	No	N/A	Different. See note 3 below table.

Device Property	VueJect Ultrasound Enhancing Agent Delivery System (K262115) (subject device)	Empower CT® and Empower CTA Injection Systems (K071378) (predicate device)	Single-use Sterile High-pressure Angiographic Syringes and Accessories (K241109) (Reference Device)	Comparison
Operating principle	Electric motor linear actuated syringe piston	Electric motor linear actuated syringe piston	N/A	Same as predicate
Power supply	Medical Grade Switching Power Supply	Medical Grade Switching Power Supply	N/A	Same as predicate
Remote start	Yes	Yes	N/A	Same as predicate
Air detection	User observed	User observed	N/A	Same as predicate
Display	Color touch screen plus membrane switches (buttons)	Color touch screen	N/A	Different. See note 4 below table.
Maximum number of stored injection protocols	N/A – Does not have stored injection protocols	50	N/A	Different. See note 5 below table.
Programmed pause	N/A	Yes	N/A	Different. See note 5 below table.
Connectivity	N/A – No connectivity	Via CT Trigger port or via a data communication method	N/A	Different. See note 6 below table.
Syringe volume	20 mL	N/A	200 mL	Different. See note 7 below table.
Extension tubing length	90 or 150 cm	N/A	20-200 cm	Different. . See note 7 below table.
Sterilization method	Gamma irradiation	N/A	Ethylene oxide	Different. See note 7 below table.

Device Property	VueJect Ultrasound Enhancing Agent Delivery System (K262115) (subject device)	Empower CT® and Empower CTA Injection Systems (K071378) (predicate device)	Single-use Sterile High-pressure Angiographic Syringes and Accessories (K241109) (Reference Device)	Comparison
Luer connectors	ISO 80369-7	N/A	ISO 80369-7	Same as reference device
Disposable materials	Polypropylene, PVC, (non-phthalate), MABS, cyclohexanone, elastomer	N/A	Polypropylene or PET, polyisoprene rubber, polydimethylsiloxane, PVC with or without phthalate, polycarbonate, ultraviolet adhesive	Different. See note 7 below table.

Note 1 – Although VueJect differs from the predicate device in its associated imaging application and the type of contrast media administered, it has the same intended use of intravenous injection of contrast agents. The injector technologies used for intravenous contrast administration are well established, and the potential risks associated with contrast delivery are not specific to a particular imaging modality. Performance testing demonstrated that VueJect is suitable for its intended use with ultrasound contrast agents and does not raise new questions of safety and effectiveness compared to legally marketed injector systems.

Note 2 - VueJect is designed for the flow rates, volumes, and operating conditions appropriate for ultrasound contrast administration. Performance verification testing demonstrated that the device operates as intended within its specified performance characteristics. These differences in operating parameters do not raise new questions of safety and effectiveness compared to the predicate device.

Note 3 - VueJect incorporates a mechanism to maintain suspension of ultrasound contrast agents during administration. Performance testing demonstrated that the system maintains microsphere suspension. This technological difference does not raise new questions of safety and effectiveness compared to the predicate device.

Note 4 - VueJect includes membrane buttons in addition to touchscreen-based user interface for initiating injections. Usability and human factors evaluations demonstrated that the device can be used safely and effectively by intended users. These features do not raise new questions of safety and effectiveness compared to the predicate device.

Note 5 - VueJect includes a feature set appropriate for its intended use. Differences in available features between VueJect and the predicate device do not affect the intended use, fundamental operating principles, or overall safety and effectiveness of the device.

Note 6 - VueJect does not include external network or device connectivity. This difference does not affect the intended use, safety, or effectiveness of the device compared to the predicate device.

Note 7 - VueJect is used with dedicated sterile disposable components designed for compatibility with the injector and intended contrast agents. Bench testing demonstrated compatibility, functional performance, packaging integrity, and sterilization effectiveness. The disposable components conform to applicable recognized standards for biocompatibility, connectors, packaging, and sterilization. The disposable components do not raise new questions of safety and effectiveness compared to those used with legally marketed injector systems.

7. Performance Data

Performance testing was successfully completed according to pre-approved verification and validation plans to ensure conformance to established performance criteria.

General System Performance

Testing verified that VueJect meets pre-determined design inputs and risk control measures, including the following:

- Fluid-mixing performance, including the ability to consistently homogenize and deliver ultrasound contrast within the limits of the contrast labeling
- General system- and component-level performance (e.g. dimensions, audible noise, disposable performance)
- Fluid delivery performance (e.g. flow rate accuracy, volume delivery accuracy, Pressure limiting accuracy)
- Ability to withstand operating atmospheric pressure, temperature and humidity

Packaging, Shelf-Life, Transportation, and Environmental Simulation

VueJect and the associated single-use disposable kits underwent packaging and device reliability testing after being subjected to simulated distribution, environmental, and accelerated aging conditions. The conditioning and testing conform to the following standards:

- ISO 11607-1 Second edition 2019-02/A1:2023 *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
- ISTA 3A:2018 *Packaging for terminally sterilized medical devices — Requirements for materials, sterile barrier systems and packaging systems*.
- ASTM D4169-23 *Standard Practice for Performance Testing of Shipping Containers and Systems*
- ASTM F1980-21 *Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices*
- ASTM F1886-16 *Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection*
- ASTM F1929 -15 *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*
- ASTM F2096-11 (2019) *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)*
- ASTM F88-23 *Standard Test Method for Seal Strength of Flexible Barrier Materials*

The testing supports a 2-year shelf life for disposable components. The service life of the VueJect Injector is 7 years.

Sterilization

The subject device is sterilized to a Sterility Assurance Level of 10^{-6} using gamma radiation. The sterilization cycle has been validated in conformance to the following standards:

- ANSI/AAMI/ISO 11137-1 :2006/ (R) 2015 & A1 :2013 & A2:2019 *Sterilization of health care products — Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
- ANSI/AAMI/ISO 11137-2:2013/(R) 2019 *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*
- ANSI/AAMI/ISO 11737-1:2018 *Sterilization of health care products - Microbiological methods — Determination of a population of microorganisms on products*
- ANSI/AAMI/ISO 11737-2:2019, *Sterilization of medical devices - Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
- ISO 11737-3:2023 *Sterilization of health care products — Microbiological methods Part 3: Bacterial endotoxin testing*

Software and Cybersecurity

VueJect software was developed and tested in accordance with the following guidance and standard:

- FDA Guidance *Content of Premarket Submissions for Device Software Functions (June 14, 2023)*
- FDA Guidance *Off-The-Shelf Software Use in Medical Devices (August 11, 2023)*
- IEC 62304:2006/A1:2016*, Medical device software. Software life-cycle processes*

Verification activities included: traceability analysis, code reviews, unit-level testing, integration-level (internal and external interfaces) testing, and system-level (functional) testing.

In addition, ACIST conducted cybersecurity testing on the subject device as recommended by:

- FDA Guidance *Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions" (February 3, 2026)*

Electromagnetic Compatibility / Electrical, Mechanical, and Thermal Safety

VueJect underwent independent testing in accordance with the following standards:

- IEC 60601-1:2005/A2:2020 (Edition 3.2) - *Medical electrical equipment –General requirements for basic safety and essential performance*
- IEC 60601-1-2:2014/AMD1:2020 (Edition 4.1) - *Medical electrical equipment — General requirements for basic safety and essential performance. Collateral standard: Electromagnetic disturbances. Requirements and tests, Amendment 1*

Cleaning and Disinfection

Cleaning and disinfection validation was performed in conformity to the following guidance and standards:

- ISO 17664-2:2021 – *Processing of Health care Product – Information to be Provided by the Medical Device Manufacturer for Processing of Medical Devices – non-critical medical devices*

- FDA Guidance - *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (issued on March 17, 2015 and amended June 9, 2017)*

Biocompatibility and Chemical Characterization

VueJect disposable components were tested as appropriate for indirect patient contacting devices per the following standards:

- ISO 10993-1:2018 – *Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- ISO 10993-4:2017 - *Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood*
- ISO 10993-5:2009 - *Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity*
- ISO 10993-10:2021 - *Biological Evaluation of Medical Devices – Part 10: Tests for Skin Sensitization*
- ISO 10993-11:2017 *Biological evaluation of medical devices - Part 11: Tests for systemic toxicity - Annex G: Information on material-mediated pyrogens*
- ISO 10993-12:2021/Amd. 1:2025 - *Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials – Amendment 1*
- ISO 10993-17:2023 - *Biological Evaluation of Medical Devices – Part 17: Toxicological Risk Assessment of Medical Device Constituents*
- ISO 10993-18:2020/ Amd. 1:2022 - *Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Medical Device Materials Within a Risk Management Process – Amendment 1*
- ISO 10993-23:2021/Amd. 1:2025 - *Biological Evaluation of Medical Devices – Part 23: Tests for Irritation – Amendment 1: Additional In Vitro Reconstructed Human Epidermis Models*
- USP 151 *Pyrogen Test*

Human Factors/ Usability

Human Factors and Usability evaluations were performed to validate the design with intended users, under simulated use conditions. Testing was conducted in compliance with the following guidance and standards:

- FDA Guidance *"Applying Human Factors and Usability Engineering to Medical Devices" (February 3, 2016)*
- FDA Guidance *"Content of Human Factors Information in Medical Device Marketing Submissions" (December 9, 2022)*
- IEC 62366-1:2015 AMD1:2020 (Edition. 1.1) - *Medical devices - Part 1: Application of usability engineering to medical devices*
- IEC 60601-1-6:2010 +A2:2021 - *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*

8. Conclusion

The non-clinical performance data fully support the safety of the device, and the verification and validation testing results demonstrate that the subject device performs as intended under the specified use conditions. The subject device has the same intended use as the predicate device, and performance testing has demonstrated that the VueJect Ultrasound Enhancing Agent Delivery System is substantially equivalent to the predicate device, the Empower CT and Empower CTA Injection Systems