May 13, 2026

ACIST Medical Systems, Inc.
Meg Daniel
Principal Regulatory Affairs Specialist
7905 Fuller Rd
Eden Prairie, Minnesota 55344

Re: K252653
Trade/Device Name: ACIST Pro™ Diagnostic System (019304); Processing Unit Bed Mount; AngioTouch Module; ACIST Pro Cart; Single Transducer Cable; Triple Transducer Cable
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: April 13, 2026
Received: April 14, 2026

Dear Meg Daniel:

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
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)*
K252653

Device Name
ACIST Pro Diagnostic System (019304);
Processing Unit Bed Mount;
AngioTouch Module;
ACIST Pro Cart;
Single Transducer Cable;
Triple Transducer Cable

Indications for Use *(Describe)*
The ACIST Pro Diagnostic System is indicated for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures.

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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K252653

1. Submitter

Name: ACIST Medical Systems, Inc.

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Eden Prairie, MN 55344
USA

Phone: 952-995-9300

Contact Person: Meg Daniel
Principal Regulatory Affairs Specialist
Email: Meg.Daniel@bracco.com

Alternative Contact: Kurtis Hunsberger
Director, Regulatory Affairs
E-mail: Kurtis.Hunsberger@bracco.com

Date Prepared: April 14, 2026

2. Device

Name of Device: ACIST Pro™ Diagnostic System (019304); Processing Unit Bed Mount; AngioTouch Module; ACIST Pro Cart; Single Transducer Cable; Triple Transducer Cable

Common Name: Automated contrast injector

Classification Name: Angiographic Injector and syringe (21 CFR 870.1650)

Regulatory Class: II

Product Code: DXT

3. Predicate Device

ACIST CVi® Contrast Delivery System, K171646

4. Device Description

The ACIST Pro™ Diagnostic System is an angiographic injection system used in interventional cardiology, radiology, and vascular surgical procedures utilizing an endovascular technique.

The ACIST Pro consists of 3 primary physical components which include software and firmware:

1. Injector - The injector houses the motors, pumps, sensing elements, and software that control the delivery of contrast and saline. The injector includes multiple features to support the safe delivery of contrast and saline. One of those features is a set of LED indicator lights that help identify status during setup and use.
2. Touchscreen – The touchscreen is used to operate the system. A cable from the touchscreen connects to the processing unit. An optional bed rail mount for the touchscreen is also available. The speaker on the touchscreen produces audible indicators to signal certain events to the user.
3. Processing unit - The processing unit provides the computing power to control the ACIST Pro System software. It communicates with x-ray, hemodynamic systems, and video distribution equipment using cables. The optional AngioTouch Module also connects to the processing unit.

The system contains two motor-driven pumps that deliver contrast media and saline to a patient via a catheter at a user-determined fixed (contrast or saline) or variable rate (contrast). The ACIST Pro offers injection modes for Cardiac, Peripheral and Structural procedures. The system can achieve a flow rate from 0.1 to 25.0 mL/s with volume ranging from 0.1 to 95.0 mL. To organize and label injection settings, the ACIST Pro offers injection groups for Cardiac, Peripheral and Structural procedures. In addition to facilitating synced injections with x-ray imaging systems, the ACIST Pro has an optional system setting where the subject device connects to the ECG out connection on hemodynamic systems to receive the defibrillation QRS marker signal. The ACIST Pro uses the ECG QRS marker signal to synchronize contrast media injection for the duration of diastole.

The ACIST Pro is mains-powered only. Based on the materials of construction, the system is MR unsafe.

Available accessories include a floor cart, AngioTouch® Module, bed mounts, and cables (including single, double and triple transducer cables, X-ray system connection cables and Hemodynamic system connection cables).

The ACIST Pro Diagnostic System must only be used with the system-specific VeraPro disposables (K252638). One of each of the following compatible devices must be used:

- VeraPro S100 Multi-Use Syringe or VeraPro S100 LV1 Syringe,
- VeraPro AMT Auto- Manifold and Transducer, and
- VeraPro FLX165 Hand Controller or VeraPro HiFi165 Hand Controller.

Refer to the 510(k) Summary of the VeraPro disposables for additional information (K252638).

The VeraPro disposable kits (K252638) provide the interface between the system and an angiographic patient catheter (not supplied by ACIST Medical Systems, Inc.). Patient connections must be made using commercially available catheters approved or cleared for use in angiographic studies.

The following supplies are required to use the ACIST Pro Diagnostic System with VeraPro disposables (K252638). They are not supplied by ACIST and are each packaged and sold separately.

- Diagnostic / guide catheter
- Sterile, commercially available 0.9% saline
- Contrast Media (refer to drug and device labeling for compatibility).

5. Indications for Use

The ACIST Pro Diagnostic System is indicated for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures.

6. Comparison of Technological Characteristics with the Predicate Device

The following table compares the technological characteristics of the ACIST Pro Diagnostic System and the predicate device.

Characteristic	Predicate Device – CVi Contrast Delivery System (K171646)	Subject Device – ACIST Pro Diagnostic System (K252653)	Comparison
Intended Use	For controlled administration of radiopaque contrast media and saline to human subjects while undergoing angiographic procedures.	Same	Same
Indications for Use	The ACIST CVi® Contrast Delivery System is indicated for controlled administration of radiopaque contrast media and saline to human subjects while undergoing angiographic procedures. The ACIST CVi® Contrast Delivery System is specifically indicated for use in angiographic procedures for the delivery of ISOVUE (Iopamidol Injection) contrast media as supplied in an Imaging Bulk Package (IBP), for a maximum of ten (10) hours. The Syringe Kit must be discarded after six (6) patient procedures. The Manifold Kit and AngioTouch Hand Controller Kit must be discarded after each patient procedure. The ACIST CVi® Contrast Delivery System is to be used only by and under quasi-continuous supervision of trained health care professionals in an appropriate licensed health care facility, in a room designated for radiological procedures that involve intravascular administration of a contrast agent.	The ACIST Pro Diagnostic System is indicated for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures.	Same indications for use language for the injector itself.Different – This difference does not change the intended use of the ACIST Pro Diagnostic System (subject device) and its predicate (K171646). No additional questions of safety and effectiveness are introduced due to this difference. The safety and effectiveness of the ACIST Pro Diagnostic System and its compatible VeraPro disposables (K252638) has been confirmed through verification and validation testing. While the subject device focuses on the injector and does not include the VeraPro disposables, the ACIST Pro Diagnostic System is designed for use with the compatible VeraPro disposables (K252638). Subject device Indications for

Characteristic	Predicate Device – CVi Contrast Delivery System (K171646)	Subject Device – ACIST Pro Diagnostic System (K252653)	Comparison
			Use are tailored to the injector and no longer include the disposables information. This is a wording clarification and not a change to the indications. The subject device combines the multi-use and single-use features of its predicate (K171646), without altering the multi-use functionality. The intended users and environment remain the same between systems.
Target Population	Human subjects who would benefit from angiographic imaging as determined by a physician.	Same	Same
Anatomical Target	Cardiac and Peripheral vasculature	Same	Same
Where Used (Clinical context)	Healthcare facility/hospital	Same	Same
Design	Computer controlled motor with belt driven actuator to advance and retract a plunger within a custom designed disposable syringe to control fluid movement to a patient connection. A second computer-controlled motor actuates a peristaltic pump to advance saline within the fluid pathway. The disposables are monitored by sensors to	Same	Same

Characteristic	Predicate Device – CVi Contrast Delivery System (K171646)	Subject Device – ACIST Pro Diagnostic System (K252653)	Comparison
	confirm valve positions as well as for gross air detection within the fluid pathway.		
Primary System Components	• Injector Head • Power Supply • Control Panel (Touchscreen display)	• Injector • Processing Unit with Power Supply • Touchscreen	Equivalent system components.
Mounting options	Cart or Bedrail mount	Same	Same
Accessory Components	• Power and communication cables • X-ray synchronization cable (optional) • Bedrail mount • Pedestal cart (optional)	• Power and Communication cables • X-ray synchronization cable (optional) • Bedrail mounts • Pedestal Cart (optional) • ECG Synchronization cables (optional) • AngioTouch Module (hand controller interface)	There is only one active hand controller location for both predicate and subject devices. The subject device's AngioTouch Module is equivalent to the predicate device's touchscreen with respect to connecting the disposable hand controller to the system. Addition of ECG Synchronization cables allows for connection of subject device ECG out connection to hemodynamic systems.
Materials	System is non patient contacting.	Same	Same
Energy	System is mains powered. No energy is delivered to the patient or healthcare provider.	Same	Same
Injection Delivery	Variable flow rate (controlled by partially depressing the hand controller contrast button)	Same	Same

<table>
<tr><th>Characteristic</th><th>Predicate Device –
CVi Contrast Delivery System (K171646)</th><th>Subject Device –
ACIST Pro Diagnostic System (K252653)</th><th>Comparison</th></tr>
<tr><td></td><td>Fixed Flow Rate (set on the touchscreen and triggered by completely depressing the hand controller contrast button)
Triggering from the X-ray system.</td><td></td><td></td></tr>
<tr><td>Injection Groups</td><td>Cardiac and Peripheral. TAVR settings can be set up manually.</td><td>Cardiac, Peripheral, and TAVR (transcatheter aortic valve replacement).</td><td>The TAVR injection group provides pre-set conditions for use during structural heart procedures.

It is possible to use settings on the predicate device to manually create injection parameters identical to the subject device TAVR injection group.</td></tr>
<tr><td>Contrast injection parameter ranges</td><td>• Flow (ml/s): 0.8-40.0
• Volume (ml): 0.8-99.9
• Maximum Pressure (psi): 200-1200
• Rise Time (s): 0.0-1.0</td><td>• Flow (ml/s): 0.1-25.0
• Volume (per injection): 0.1-95.0
• Maximum Pressure (psi): 200-1200
• Rise Time (s): 0.0-1.0</td><td>Refinement of default injection parameters. The maximum flow, volume, pressure, and rise time are within the predicate device’s parameters.</td></tr>
<tr><td>Injector Presets</td><td>
<table>
<tr><th>Group</th><th>Subgroup</th><th>Flow (mL/s)</th><th>Volume (mL)</th><th>Rise time (s)</th></tr>
<tr><td rowspan="4">Cardiac</td><td>LCA</td><td>4.0</td><td>10.0</td><td>0.5</td></tr>
<tr><td>RCA</td><td>3.0</td><td>6.0</td><td>0.5</td></tr>
<tr><td>LV/Ao</td><td>13.0</td><td>45.0</td><td>0.2</td></tr>
<tr><td>Other</td><td>3.0</td><td>6.0</td><td>0.5</td></tr>
<tr><td rowspan="4">Peripheral</td><td>Pigtail</td><td>0.0</td><td>0.0</td><td>0.5</td></tr>
<tr><td>Selective</td><td>0.0</td><td>0.0</td><td>0.3</td></tr>
<tr><td>Micro</td><td>0.0</td><td>0.0</td><td>0.0</td></tr>
<tr><td>Other</td><td>0.0</td><td>0.0</td><td>0.5</td></tr>
</table>
</td><td>
<table>
<tr><th>Group</th><th>Subgroup</th><th>Flow (mL/s)</th><th>Volume (mL)</th><th>Rise time (s)</th></tr>
<tr><td rowspan="3">Cardiac</td><td>LCA</td><td>4.0</td><td>6.0</td><td>0.2</td></tr>
<tr><td>RCA</td><td>3.0</td><td>5.0</td><td>0.2</td></tr>
<tr><td>LV/Aorta</td><td>12.0</td><td>20.0</td><td>0.5</td></tr>
<tr><td rowspan="3">Peripheral</td><td>Small</td><td>5.0</td><td>10.0</td><td>0.2</td></tr>
<tr><td>Medium</td><td>10.0</td><td>20.0</td><td>0.2</td></tr>
<tr><td>Large</td><td>15.0</td><td>30.0</td><td>0.5</td></tr>
<tr><td rowspan="4">TAVR</td><td>Aorta</td><td>20.0</td><td>15.0</td><td>0.0</td></tr>
<tr><td>Iliac</td><td>8.0</td><td>12.0</td><td>0.2</td></tr>
<tr><td>Femoral</td><td>3.0</td><td>5.0</td><td>0.2</td></tr>
</table>
</td><td>The subject device injector presets for existing subgroups are within the predicate device’s injector presets and overall injection parameters.</td></tr>
</table>

Characteristic	Predicate Device – CVi Contrast Delivery System (K171646)	Subject Device – ACIST Pro Diagnostic System (K252653)	Comparison
Contrast Tracking	Amount of contrast delivered to patient displayed.	Amount of contrast delivered to patient and total contrast used displayed. User can set a "contrast target limit."	Both subject and predicate device display contrast delivered to the patient. The subject device also displays total contrast used. The subject device allows users to optionally set a "contrast target limit." This displays as a contrast delivered tracking bar and a percentage of contrast delivered to the patient compared to the target limit.
Syringe Auto refill	Yes	Same	Same
Software-controlled Required Syringe Change	Yes	Same	Same
RFID reader/writer	No	Yes	The subject device has an RFID reader/writer to identify VeraPro patient tubing. This feature aims to prevent disposable reuse and to effectively evacuate air from the entire tubing length while minimizing contrast waste.

Characteristic	Predicate Device – CVi Contrast Delivery System (K171646)	Subject Device – ACIST Pro Diagnostic System (K252653)	Comparison
Equipped with Air Column Detect Sensor	Yes	Same	Both devices are equipped with an air column detection sensor. The location of the sensor has moved from being clamped onto the syringe kit of the predicate device to being mounted on the injector of the subject device.
Contrast Usage Monitoring	Yes	Same	Same
KVO (Keep Vessel Open) functionality	Yes	No	Function not implemented.
X-Ray Imaging System Compatibility	Yes	Same	Same
Hemodynamic Signal	Available hemodynamic backplate and adapter allow for transmitting up to 3 invasive blood pressure signals for display on the facility's hemodynamic system.	Available hemodynamic backplate and adapter allow for transmitting up to 3 invasive blood pressure signals for display on the facility's hemodynamic system. User can zero and calibrate the hemodynamic signal from the subject device at bedside.	Both devices allow for transmitting the invasive blood pressure signal for display on the facility's hemodynamic system. There is no change in ability to transmit the signal as compared to the predicate. The subject device allows for zeroing and calibrating the hemodynamic signal at bedside rather than from the control room. There is no change in ability to zero or

Characteristic	Predicate Device – CVi Contrast Delivery System (K171646)	Subject Device – ACIST Pro Diagnostic System (K252653)	Comparison
			calibrate signal on the facility's hemodynamic system.
Hemodynamic System Compatibility (ECG Sync)	No	Optional system setting where the subject device connects to the ECG out connection on hemodynamic systems to receive the defibrillation QRS marker signal. System uses the ECG QRS marker signal to synchronize contrast media injection with the duration of diastole.	The optional system setting on the subject device allows users to sync contrast media injection with the duration of diastole. User-initiated injections can still be selected on the subject device and perform equivalent to the predicate device.
Operating System	DOS	Windows 10 IoT Enterprise LTSC	Operating System has been updated to facilitate software changes and cybersecurity updates.

DESIGN

The ACIST Pro has the same fundamental technology and principle of operation as the predicate device. Both the subject and predicate devices contain two motor-driven pumps that deliver contrast media and saline to a patient via a catheter at a user-determined fixed (contrast or saline) or variable rate (contrast). Both devices have similar system components, accessories, and mounting options.

MATERIALS

Both the subject and predicate devices are non-patient contacting.

ENERGY SOURCES

Both the subject and predicate devices are mains powered. Energy delivery to the patient or healthcare provider is not a functional aspect of either device.

OTHER KEY TECHNOLOGICAL FEATURES

The subject and predicate devices both offer “cardiac and peripheral injection groups.” When the predicate device is powered up by the user, the default injection parameters are displayed as listed in the comparison table (ex. Pigtail catheter with flow of 0.0 mL/s and volume of 0.0mL). The subject device adds a “TAVR” (Transcatheter Aortic Valve Replacement) to the injection groups. It is possible to use settings on the predicate device to manually create injection parameters identical to all subject device injection groups, including the Peripheral and TAVR injection groups. Therefore, the modifications to the subject device injector presets do not adversely impact the safety and effectiveness of the subject device compared to the predicate device.

The subject and predicate devices both offer default “contrast injection parameter ranges.” ACIST has refined the default injection parameters on the subject device - the maximum flow, volume, pressure, and rise time are all within the predicate device’s parameters. The lowered minimum flow rate and volume range do not adversely impact the safety and effectiveness of the subject device compared to the predicate device as the user continues to determine the necessary flow rate and total contrast delivered to patient.

The subject and predicate devices both offer safety features such as tracking total contrast delivered to patient, software-controlled required syringe changes and air column detection. The subject device allows users to optionally set a “contrast target limit” which displays as a contrast delivered tracking bar and a percentage of contrast delivered to the patient compared to the target limit. This enables the user to continuously verify the contrast delivered to the patient throughout the case. Also, the subject device adds an RFID reader/writer to identify VeraPro patient tubing. This feature aims to prevent disposable reuse and to effectively evacuate air from the entire tubing length while minimizing contrast waste. These additional safety features do not adversely impact the safety and effectiveness of the subject device compared to the predicate device.

The predicate device offered a "Keep Vessel Open” which allowed the user to dispense saline at a programmable rate; however, this feature was rarely employed by users and carried the potential for unintended delivery of contrast in the patient tubing to the patient. Therefore, the KVO feature has not been implemented in the subject device. Absence of this feature is not expected to adversely impact the safety and effectiveness of the subject device compared to the predicate device.

Both devices can also facilitate synced injections with the x-ray imaging systems.

The subject and predicate devices both collect the invasive blood pressure signal via the injector transducer backplate and display the signal on the facility's hemodynamic system. The subject device allows for zeroing and calibrating of the hemodynamic signal at bedside rather than only from the control room. There is no change in the user's ability to view, zero or calibrate the signal on the hospital hemodynamic system.

The subject device has additional hemodynamic system compatibility whereby the system uses the ECG QRS marker signal to synchronize contrast media injection with the onset of diastole ("ECG Sync"). The optional ECG Sync system setting on the subject device allows users to sync contrast media injection with the duration of diastole. User-initiated injections can still be selected on the subject device and perform in a manner equivalent to the predicate device. This additional feature does not adversely impact the safety and effectiveness of the subject device compared to the predicate device.

The subject and predicate devices both include software and firmware. The operating system on the subject device has been updated to Windows 10 IoT Enterprise LTSC to facilitate software and cybersecurity updates.

7. Performance Data

The subject device's hardware and software were tested in accordance with ACIST-approved verification and validation plans to ensure conformance with pre-determined acceptance criteria.

Reprocessing / Cleaning

The subject device demonstrated compliance with the following device-specific guidance and standards:

- AAMI TIR12:2020 – *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*
- ISO 17664-2:2021 – *Processing of Heath care Product – Information to be Provided by the Medical Device Manufacturer for Processing of Medical Devices – non-critical medical devices*
- U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Heath, Office of Device Evaluation - *Reprocessing Medical Devices in Heath Care Settings: Validation Methods and Labeling* (issued on March 17, 2015 and amended June 9, 2017).

Shelf Life

The subject device underwent packaging and device reliability testing after being subjected to conditions in compliance with:

- ASTM D4169-22 - *Standard Practice for Performance Testing of Shipping Containers and Systems.*

Verification results support a lifetime in use of 7 years from the date of product installation when the system is operated according to the instructions and maintenance activities are performed.

Software/Firmware and Cybersecurity

The subject device underwent software verification testing in compliance 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/A1:2015 (ed 1.1) - *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 in compliance with:

- 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

The subject device 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.*

Bench Testing

The subject device underwent testing in compliance with applicable portions of the following guidance and standards:

- FDA Guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions" (December 2019)
- ANSI/AAMI BP22:1994 (2016) - *Blood Pressure Transducers*
- ISO 19054:2005 - *Rail systems for supporting medical equipment.*

In addition, the subject device underwent verification testing to ensure its performance met design inputs and risk control measures, including the following items:

- General system- and component-level performance (ex. dimensions, audible noise, signal timing, sensor accuracy, input and output signals)
- Fluid delivery performance (ex. flow rate accuracy, volume delivery accuracy, Pressure limiting accuracy)
- Ability to withstand operating atmospheric pressure, temperature and humidity
- Device interoperability and compatibility with 3rd party hemodynamic and simulated imaging systems.

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 (Ed. 1.1) - *Medical devices - Part 1: Application of usability engineering to medical devices*
- IEC 60601-1-6:2010 (Ed 3.0) - *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.*

PERFORMANCE TESTING SUMMARY

Verification and validation activities conducted on the subject device did not produce any unexpected issues of safety or effectiveness. The results of the design verification and validation testing, including the human factors validation testing, demonstrate that the subject device performed as intended.

8. Conclusion

The non-clinical data fully support the safety of the device and the results of verification and validation testing demonstrate that the subject device performs as intended in the specified use conditions. No clinical testing was required or performed to support this application.

There are no significantly modified existing risks between the predicate and subject devices. The similarity in the predicate and subject devices' intended use and design and completed performance testing support a substantially equivalent determination.