May 13, 2026

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

Re: K252638
Trade/Device Name: VeraPro S100 Multi-Use Syringe (018808); VeraPro S100 LV1 Low Viscosity Singel-Use Syringe (018811); VeraPro AMT Auto-Manifold and Transducer (018814); VeraPro AngioTouch FLX165 Hand Controller Kit (018806); VeraPro AngioTouch HiFi165 Hand Controller Kit (018804)
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 Bobbie Daughters:

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)*
K252638

Device Name
VeraPro S100 Multi-Use Syringe (018808);
VeraPro S100 LV1 Low Viscosity Single-Use Syringe (018811);
VeraPro AMT Auto-Manifold and Transducer (018814);
VeraPro AngioTouch FLX165 Hand Controller Kit (018806);
VeraPro AngioTouch HiFi165 Hand Controller Kit (018804)

Indications for Use *(Describe)*

1. VeraPro S100 Multi-Use Syringe
The VeraPro Syringe is intended for use with the ACIST Pro Diagnostic System for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures.

The VeraPro S100 is for multi-use and must be discarded after five (5) patient procedures. In multi-use mode, the VeraProS100 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.

2. VeraPro S100 LV1 Low Viscosity Single-Use Syringe
The VeraPro Syringe is intended for use with the ACIST Pro Diagnostic System for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures.

The VeraPro S100 LV1 is for single-use and must be discarded after each patient procedure.

3. VeraPro AMT Auto-Manifold and Transducer
The VeraPro Auto-Manifold and Transducer is intended for use with the ACIST Pro Diagnostic System for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures.

The VeraPro AMT is for single-use and must be discarded after each patient procedure.

4. VeraPro AngioTouch HiFi 165 Hand Controller Kit
VeraPro AngioTouch FLX 165 Hand Controller Kit
The VeraPro AngioTouch Hand Controller Kit is intended for use with the ACIST Pro Diagnostic System (ACIST Pro System) for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures.

The VeraPro AngioTouch HiFi 165 and FLX 165 Hand Controller Kits are for single-use and must be discarded after each patient procedure.

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 Complying with 21 CFR 807.92
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=807.92

1. Submitter

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Date Prepared: April 13, 2026

2. Device

Name of Device:	VeraPro S100 Multi-Use Syringe (018808), VeraPro S100 LV1 Low Viscosity Single-Use Syringe (018811), VeraPro AMT Auto-Manifold and Transducer (018814), VeraPro AngioTouch® FLX 165 Hand Controller Kit (018806), VeraPro AngioTouch® HiFi 165 Hand Controller Kit (018804)
Common or Usual Name:	Contrast Management System
Classification Name:	Angiographic Injector and Syringe (21 CFR 870.1650)
Regulatory Class:	II
Product Code:	DXT

3. Predicate Device

Name of Device:	ACIST CVi®/CVi ®1 Contrast Delivery System, K203004
Common or Usual Name:	Contrast Management System
Classification Name:	Angiographic Injector and Syringe (21 CFR 870.1650)
Regulatory Class:	II
Product Code:	DXT

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

4. Device Description

The VeraPro disposables are intended to be used for the controlled administration of radiopaque contrast media for angiographic procedures. VeraPro disposables include the VeraPro AMT Auto-Manifold and Transducer, VeraPro S100 syringe family (S100, S100 LV1), and VeraPro AngioTouch Hand Controller family (FLX 165, HiFi 165). VeraPro disposables provide the interface between the ACIST Pro Diagnostic System K252653, (herein referred to as "ACIST Pro") and a user-supplied patient catheter.

All disposable kits are custom-designed and manufactured. Each is provided sterile and preassembled to minimize the possibility of interconnection in the wrong manner while ensuring positive connections. The VeraPro disposables are specifically used in conjunction with the ACIST Pro (K252653) and enable the delivery of saline and contrast in a unidirectional path to the patient.

One of each (syringe, manifold, hand controller) of the following is required to create the unidirectional saline and contrast paths from the ACIST Pro to the patient. Together, these components form the essential elements of the "contrast management system."

- VeraPro Syringe (VeraPro S100 or VeraPro S100 LV1)
- VeraPro Auto-Manifold and Transducer (VeraPro AMT)
- VeraPro AngioTouch® Hand Controller Kit (VeraPro HiFi 165 or VeraPro FLX 165)

The VeraPro Disposables are intended for use only with the ACIST Pro Diagnostic System. Refer to the ACIST Pro 510(k) Summary of K252653 for additional information.

VeraPro S100 Multi-Use Syringe
VeraPro S100 LV1 Low Viscosity Single-Use Syringe

The VeraPro syringe family includes two variants, the VeraPro S100 LV1 Low-Viscosity Single use Syringe, and VeraPro S100 Multi-Use Syringe. The VeraPro syringes are part of the contrast management system and are provided sterile.

The VeraPro S100 LV1 is a single use syringe and includes a 100mL syringe with a contrast spike and contrast tubing. The S100 LV1 is for use with low viscosity (LV) contrast ranges of 1-15 centipoise (cP) or equivalent.

The VeraPro S100 is a multi-use syringe and includes a 100mL syringe with a contrast spike and contrast tubing. In addition, the S100 includes a slide clamp and five (5) disinfecting luer caps. The slide clamp is used to control the flow of contrast into the syringe when changing the single use VeraPro AMT kit between patients. The caps are screwed onto the end of the syringe's male luer connector to maintain a closed system between procedures. The VeraPro S100 is for multi-use and must be discarded after five (5) patient procedures. The S100 syringe is for use with high viscosity contrast ranges of 4.6 – 26.6 cP.

VeraPro AMT Auto-Manifold and Transducer

The VeraPro AMT Auto-Manifold and Transducer ("VeraPro AMT") is another element of the contrast management system. The AMT kit includes a saline spike, tubing, transducer cartridge and manifold, and a flush bag. The device is provided sterile for single use and must be discarded between cases.

VeraPro AngioTouch HiFi 165 Hand Controller Kit
VeraPro AngioTouch FLX 165 Hand Controller Kit

The VeraPro AngioTouch Hand Controller Kit is for use with the ACIST Pro System (K252653) to provide precise control of contrast and saline in angiographic procedures. The VeraPro AngioTouch Hand Controller family includes two variants, the VeraPro HiFi 165 and the VeraPro FLX 165, designed with enhanced or standard high-pressure tubing options.

- VeraPro HiFi 165 - Customized, co-extruded high-pressure (enhanced) patient tubing designed to facilitate high fidelity pressure waveforms.
- VeraPro FLX 165 - A hybrid of two customized (co-extruded and braided), high-pressure patient tubing types designed for flexibility.

Each available kit contains an ergonomic AngioTouch® pneumatic hand controller, a 3-way high-pressure stopcock with rotating luer, HiFi or FLX high-pressure patient tubing with a rotating luer connection, and a RFID tag. The hand controller is provided sterile for single use and must be discarded between cases.

The following supplies are required to use the VeraPro disposables with the ACIST Pro Diagnostic System (K252653). 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

VeraPro S100 Multi-Use Syringe

The VeraPro Syringe is intended for use with the ACIST Pro Diagnostic System for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures.

The VeraPro S100 is for multi-use and must be discarded after five (5) patient procedures. In multi-use mode, the VeraPro S100 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.

VeraPro S100 LV1 Low Viscosity Single-Use Syringe

The VeraPro Syringe is intended for use with the ACIST Pro Diagnostic System for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures.

The VeraPro S100 LV1 is for single-use and must be discarded after each patient procedure.

VeraPro AMT Auto-Manifold and Transducer

The VeraPro Auto-Manifold and Transducer is intended for use with the ACIST Pro Diagnostic System for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures.

The VeraPro AMT is for single-use and must be discarded after each patient procedure.

VeraPro AngioTouch HiFi 165 Hand Controller Kit
VeraPro AngioTouch FLX 165 Hand Controller Kit

The VeraPro AngioTouch Hand Controller Kit is intended for use with the ACIST Pro Diagnostic System (ACIST Pro System) for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures.

The VeraPro AngioTouch HiFi 165 and FLX 165 Hand Controller Kits are for single-use and must be discarded after each patient procedure.

6. Comparison of Technological Characteristics with the Predicate Device

The following tables compare the technological characteristics of the VeraPro Disposables with the predicate device.

Table 1: Substantial Equivalence Table –VeraPro S100 Multi-Use Syringe

Characteristic	Predicate Device- A2000 Syringe kit (K203004)	Subject Device- VeraPro S100 Multi-Use Syringe (K252638)	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 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 VeraPro Syringe is intended for use with the ACIST Pro Diagnostic System for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures. The VeraPro S100 is for multi-use and must be discarded after five (5) patient procedures. In multi-use mode, the VeraPro S100 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.	Different - This difference does not change the intended use of the device. No additional questions of safety and effectiveness are introduced due to this difference when compared to the predicate device. The performance of the VeraPro Disposables and the compatible injector system (K252653) has been confirmed through verification and validation testing. While the subject device is limited to the disposable components and does not include the injector, the VeraPro disposables are only intended for use with the ACIST Pro Diagnostic System (K252653). Subject device Indications for Use are tailored to the disposable syringe and no longer include the system-level information. This is a wording clarification and not a change to the indications. There is no change to the intended users or use environment for the subject device compared to the predicate. The information describing intended users and use environment is now included in the Intended Users section of the VeraPro IFUs and the ACIST Pro User Guide (K252653).
Usability	Multi-use	Same	Same
Viscosity Range	4.6-26.6 cP	Same	Same

Characteristic	Predicate Device- A2000 Syringe kit (K203004)	Subject Device- VeraPro S100 Multi-Use Syringe (K252638)	Comparison
Syringe Body	Polycarbonate	Same	Same
Syringe Coating (ID)	Polydimethylsiloxane Silicone Fluid	Same	Same
Wiper	Ethylene Propylene Diene Monomer (EPDM) Rubber	Same	Same
Wiper Support	Acrylonitrile butadiene styrene (ABS)	Same	Same
Contrast O-Ring	Ethylene Propylene Diene Monomer	Same	Same
Valve Check	Stainless Steel Ball	Same	Same
Contrast Tubing (inlet tubing)	Polyvinyl Chloride	Same	Same
Contrast Outlet Tubing (interconnect tubing)	Polyurethane, Nylon Braid, 1.21 inches in length	Polyurethane, Nylon Braid, 1.9 inches in length	Outlet tubing between syringe and rotator lengthened from 1.21 inches on CVi to 1.9 inches on the VeraPro syringe to accommodate the new ACIST Pro. There is no change to the material. This modification does not adversely impact the safety and effectiveness of the subject device compared to the predicate device.
Rotator	Body: Polycarbonate O-Ring: Silicone Rubber	Same	Same
Disinfecting Cap	HDPE, 70% Isopropanol	Same	Same
Sterilization Method	Gamma Irradiation	Same	Same
Sterility Assurance Level	10^{-6}	Same	Same

Characteristic	Predicate Device- A2000 Syringe kit (K203004)	Subject Device- VeraPro S100 Multi-Use Syringe (K252638)	Comparison
Packaging	Polyethylene/Nylon Laminate with Tyvek 1073B Strip Pouch	Same	Same
Shelf-Life	18 Months	18 Months	Same

Table 2: Substantial Equivalence Table –VeraPro S100 LV1 Low Viscosity Single Use Syringe

Characteristics	Predicate Device- A1000V Syringe kit (K203004)	Subject Device- VeraPro S100 LV1 Low ViscositySingle-Use Syringe (K252638)	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 CVi1 Contrast Delivery System is indicated for controlled administration of radiopaque contrast media and saline to human subjects while undergoing angiographic procedures. The CVi1 Syringe Kits, Manifold Kit and AngioTouch® Hand Controller Kit must be discarded after each patient procedure. The CVi1 Syringe Kits are also indicated for single patient use with ACIST CVi® Contrast Delivery Systems. The ACIST CVi®1 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 VeraPro Syringe is intended for use with the ACIST Pro Diagnostic System for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures. The VeraPro S100 LV1 is for single use and must be discarded after each patient procedure.	Different - This difference does not change the intended use of the device. No additional questions of safety and effectiveness are introduced due to this difference when compared to the predicate device. The performance of the VeraPro Disposables and the compatible injector system (K252653) has been confirmed through verification and validation testing. While the subject device is limited to the disposable components and does not include the injector, the VeraPro disposables are only intended for use with the ACIST Pro Diagnostic System (K252653). Subject device Indications for Use are tailored to the disposable syringe and no longer include the system-level information. This is a wording clarification and not a change to the indications. There is no change to the intended users or use environment for the subject device compared to the predicate. The information describing intended users and use environment is now included in the Intended Users section of the VeraPro IFUs and the ACIST Pro User Guide (K252653).
Usability	Single Use	Same	Same
Viscosity Range	1.0-15.0 cP	Same	Same

Characteristics	Predicate Device- A1000V Syringe kit (K203004)	Subject Device- VeraPro S100 LV1 Low ViscositySingle-Use Syringe (K252638)	Comparison
Syringe Body	Polycarbonate	Same	Same
Syringe Coating (ID)	Polydimethylsiloxane Silicone Fluid	Same	Same
Wiper	Ethylene Propylene Diene Monomer (EPDM) Rubber	Same	Same
Wiper Support	Acrylonitrile butadiene styrene (ABS)	Same	Same
Contrast O-Ring	Ethylene Propylene Diene Monomer	Same	Same
Valve Check	Plastic Scepter	Same	Same
Contrast Tubing (inlet tubing)	Polyvinyl Chloride	Same	Same
Contrast Outlet Tubing (interconnect tubing)	Polyurethane, Nylon Braid, 1.21 inches in length	Polyurethane, Nylon Braid, 1.9 inches in length	Outlet tubing between syringe and rotator lengthened from 1.21 inches on CVi to 1.9 inches on the VeraPro syringe to accommodate the new ACIST Pro. There is no change to the material. This modification does not adversely impact the safety and effectiveness of the subject device compared to the predicate device.
Rotator	Body: Polycarbonate O-Ring: Silicone	Same	Same
Sterilization Method	Gamma Irradiation	Same	Same
Sterility Assurance Level	10^{-6}	Same	Same

Characteristics	Predicate Device- A1000V Syringe kit (K203004)	Subject Device- VeraPro S100 LV1 Low ViscositySingle-Use Syringe (K252638)	Comparison
Packaging	Polyethylene/Nylon Laminate with Tyvek 1073B Strip Pouch	Same	Same
Shelf-Life	18 months	18 Months	Same

Table 3 Substantial Equivalence Table – VeraPro AMT Auto-Manifold and Transducer

Characteristic	Predicate Device- BT2000 Manifold Kit (K203004)	Subject Device – VeraPro AMT Auto-Manifold and Transducer (K252638)	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 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-	The VeraPro Auto-Manifold and Transducer is intended for use with the ACIST Pro Diagnostic System for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures. The VeraPro AMT is for single use and must be discarded after each patient procedure.	Different - This difference does not change the intended use of the device. No additional questions of safety and effectiveness are introduced due to this difference when compared to the predicate device. The performance of the VeraPro Disposables and the compatible injector system (K252653) has been confirmed through verification and validation testing. While the subject device is limited to the disposable components and does not include the injector, the VeraPro disposables are only intended for use with the ACIST Pro Diagnostic System (K252653). Subject device Indications for Use are tailored to the disposable manifold and transducer and no longer include the system-level information. This is a wording clarification and not a change to the

Characteristic	Predicate Device- BT2000 Manifold Kit (K203004)	Subject Device – VeraPro AMT Auto-Manifold and Transducer (K252638)	Comparison
	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.		indications. There is no change to the intended users or use environment for the subject device compared to the predicate. The information describing intended users and use environment is now included in the Intended Users section of the VeraPro IFUs and the ACIST Pro User Guide (K252653).
Usability	Single use	Same	Same
Fluid Waste Receptacle	20 ml syringe (1)	75 ml Flush Bag (1)	Removal of 20 ml syringe and addition of 75 ml flush bag to provide additional capacity for purging of fluids during setup (waste).
Manifold Body	Polycarbonate	Same	Same
Manifold Coating (ID)	Polydimethylsiloxane Silicone Fluid	Same	Same
Manifold Shaft	Acrylic	Same	Same
Spring	Stainless Steel	Same	Same
O-Ring	Ethylene Propylene Diene Monomer	Same	Same
Peristaltic Pump Tubing	Polyvinyl Chloride	Same	Same
Contrast Tubing	Polyurethane, Nylon Braid; Fixed Luers	Same	Same
Peristaltic Pump Tubing Retention **(Tubing guides)**	N/A	2 Peristaltic Retaining Clips	Addition of 2 Peristaltic Retaining Clips on the saline tubing line used for tubing retention in the peristaltic pump drawer. There are no fluid-path changes compared to the

Characteristic	Predicate Device- BT2000 Manifold Kit (K203004)	Subject Device – VeraPro AMT Auto-Manifold and Transducer (K252638)	Comparison
			predicate device. The Retaining Clips are external to fluid path.
Transducer Tubing	Polyurethane	Same	Same
Universal Luer Caps	Polycarbonate	Same	Same
Sterilization Method	Gamma Irradiation	Same	Same
Sterility Assurance Level	10^{-6}	Same	Same
Packaging	Polyethylene/Nylon Laminate with Tyvek 1073B Strip Pouch	Same	Same
Shelf-Life	18 months	Same	Same

Table 4: Substantial Equivalence Table - VeraPro AngioTouch HiFi 165 and FLX 165 Hand Controller Kit

Characteristic	Predicate Device- AngioTouch Hand Controller and patient tubing Kit (AT-P65, AT-X65) K203004	Subject Device - VeraPro AngioTouch HiFi 165 Hand Controller Kit, VeraPro AngioTouch FLX 165 Hand Controller Kit (K252638)	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 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 VeraPro AngioTouch Hand Controller Kit is intended for use with the ACIST Pro Diagnostic System for controlled administration of radiopaque contrast media and saline to human subjects undergoing angiographic procedures. The VeraPro AngioTouch HiFi 165 and FLX 165 Hand Controller Kits are for single-use and must be discarded after each patient procedure.	Different - This difference does not change the intended use of the device. No additional questions of safety and effectiveness are introduced due to this difference when compared to the predicate device. The performance of the VeraPro Disposables and the compatible injector system (K252653) has been confirmed through verification and validation testing. While the subject device is limited to the disposable components and does not include the injector, the VeraPro disposables are only intended for use with the ACIST Pro Diagnostic System (K252653). Subject device Indications for Use are tailored to the disposable hand controller kits and no longer include the system-level information. This is a wording clarification and not a change to the indications. There is no change to the intended users or use environment for the subject device compared to the predicate. The information describing intended users and use environment is now included in the Intended Users section of the VeraPro IFUs and the ACIST Pro User Guide (K252653).
Usability	Single Use	Same	Same

Characteristic	Predicate Device- AngioTouch Hand Controller and patient tubing Kit (AT-P65, AT-X65) K203004	Subject Device - VeraPro AngioTouch HiFi 165 Hand Controller Kit, VeraPro AngioTouch FLX 165 Hand Controller Kit (K252638)	Comparison
Housing	ABS	Same	Same
Bladders	Polyvinyl Chloride	Same	Same
RFID Tag	No	Yes	An RFID tag has been added to the high-pressure tubing to guard against disposable re-use and prevent off-label use of potentially incompatible components which may diminish the ability to detect gross safety errors (ex. Air column detection). This additional feature does not adversely impact the safety and effectiveness of the subject device compared to the predicate device.
Twin Tubing (pneumatic)	Polyvinyl Chloride	Same	Same
High-pressure Tubing	AT-P65: Polyurethane, Nylon Braid; fixed luers AT-X65: Polyamide/Polyurethane, no braid; rotating luers	FLX 165: Similar HiFi 165: Same	FLX 165: The FLX 165 tubing is a hybrid of the AT-P65 and AT-X65. A 13" Polyamide/Polyurethane, unbraided section of tubing is bonded to a 51" section of braided high-pressure tubing to improve performance of the air column detect. This modification does not adversely impact the safety and effectiveness of the subject device compared to the predicate device.
High-pressure Tubing Length	65 inches (165 centimeters)	Same	Same
Sterilization Method	Ethylene Oxide	Same	Same

Characteristic	Predicate Device- AngioTouch Hand Controller and patient tubing Kit (AT-P65, AT-X65) K203004	Subject Device - VeraPro AngioTouch HiFi 165 Hand Controller Kit, VeraPro AngioTouch FLX 165 Hand Controller Kit (K252638)	Comparison
Sterility Assurance Level	10^{-6}	Same	Same
Packaging	AT-P65 and AT-X65: Polyethylene/nylon laminate with Tyvek 2FS or 1073B Tyvek	Same	Same
Shelf-Life	AT-P65: 18 months AT-X65: 24 months	Same	Same. The Shelf life for HiFi 165 is the same as AT-X65 and the FLX 165 is the same as AT-P65.

Comparison of Indications for Use
Both the subject and predicate devices have the same intended use for the controlled administration of radiopaque contrast media and saline to human subjects while undergoing angiographic procedures. The revisions in the subject device's Indications for Use do not alter the intended diagnostic use of the device, nor do they affect the safety and effectiveness of the subject device relative to the predicate.

Comparison of Technological Characteristics
The proposed VeraPro disposables have the same fundamental technology and principle of operation as the predicate, ACIST CVi disposables (K203004).

The ACIST VeraPro Disposables compose the contrast management system providing a sterile fluid path for unidirectional contrast delivery to patients undergoing angiographic procedures. The VeraPro brand disposable kits are specifically used in conjunction with the ACIST Pro Diagnostic System. The VeraPro disposable kits provide the interface between the system and an angiographic patient catheter (not supplied by ACIST Medical Systems, Inc.).

There are no new materials introduced into the fluid path of the VeraPro disposables as compared to the predicate. The function and intended use are unchanged between the subject and predicate device. The key differences between the predicate and the VeraPro disposables are summarized below:

- The VeraPro Hand Controller Kit has a molded RFID tag for traceability, and a portion of the braided tubing in the FLX 165 is replaced with the same coextruded high-pressure tubing used in the predicate AT X65 patient line tubing to provide additional flexibility.
- The VeraPro Syringe kit has slightly longer outlet tubing for easier connection.
- The VeraPro Manifold/Transducer kit includes the replacement of the hand syringe with a flush bag for waste collection and the addition of external retainers to the peristaltic tubing.

The subject device VeraPro disposables are substantially equivalent to the predicate device in intended use and technological characteristics and are as safe and effective as the predicate device for their intended purpose. No new or different questions of safety or effectiveness were raised with the enhancements to the subject device.

7. Performance Data

The following performance data was provided in support of the substantial equivalence determination. The VeraPro disposables were tested in accordance with ACIST-approved verification and validation plans to ensure conformance with pre-determined acceptance criteria.

Bench Testing
The subject device passed all 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)
- ISO 80369-1:2018 Second edition - *Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements*
- ISO 80369-7:2021 Second edition - *Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connections for intravascular or hypodermic needles.*

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

- Bond Pull: Measures the force required to break the bond between two materials.
- Burst: Assesses the pressure at which a device or component fails.
- Durability: Evaluates the device's ability to withstand repeated use or stress.
- Flow: Ensures the rate at which fluid moves through a device.
- Pressure: Tests the device's ability to withstand or operate under specific pressure conditions.

- Microbial Ingress and Cross-Contamination: Evaluates the device's ability to maintain a sealed fluid pathway.
- Particulate: Ensures the device delivers less than the maximum allowable particulate density per USP <788>.

Biocompatibility

Testing conducted in compliance with FDA-recognized standards for the following endpoints met all applicable acceptance criteria:

- ISO 10993-1:2018 *Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process*
- Cytotoxicity: Assessed using ISO 10993-5:2009/R(2022), *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity* demonstrating that VeraPro shows no cytotoxic effects, consistent with the biocompatibility profile of the predicate.
- Sensitization, Irritation or Intracutaneous Reactivity: Evaluated per ISO 10993-10:2010/(R)2014, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization* VeraPro showed results comparable to the predicate indicating no sensitization responses and no irritation or intradermal reactivity.
- Acute Systemic Toxicity and Pyrogenicity: Conducted as per ISO 10993-11:2017 *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*, both subject and predicate device results showed no signs of acute systemic toxicity and are considered non-pyrogenic.
- Hemocompatibility: Following ISO 10993-4:2017, *Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood,* VeraPro demonstrates non-hemolytic properties, matching the performance of the predicate.

Chemical characterization

The subject device underwent testing in compliance with the following standards to ensure an acceptable toxicological risk profile:

- ISO 10993-1:2018 *Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process*
- Chemical characterization and analysis conducted per ISO 10993-18:2020 - *Biological evaluation of medical devices- Part 18: Chemical characterization of medical device materials within a risk management process* confirmed that VeraPro materials are chemically equivalent with those of the predicate.
- Extractables and Leachables Analysis Per ISO 10993-17:2002/(R)2012 - *Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances*, A toxicological risk assessment of extractables and leachables showed that VeraPro has the same risk profile as the predicate, and supports a conclusion of tolerable risk of carcinogenicity, genotoxicity/mutagenicity, reproductive toxicity, and endocrine disruption to patients associated with exposure to the identified compounds.

Sterilization

The subject device is sterilized using ethylene oxide (EO) for the hand controller and gamma radiation for the manifold and syringe. The device is sterilized to a Sterility Assurance Level (SAL) of $10^{-6,}$ demonstrating compliance with the required standards for sterility. The sterilization processes are validated according to the following standards:

- ISO 11135:2014/A1:2018 - *Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices*
- ISO 10993-7:2008+A1:2019 - *Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals*
- ISO 11137-1:2006/ AMD2:2018 - *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.*
- ISO 11137-2:2013/ AMD1:2022 - *Sterilization of health care products. Radiation — Establishing the sterilization dose*
- ISO 11737-1:2018/AMD1:2021 - Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products.

Packaging and Shelf Life

The subject device underwent packaging, device functional testing, and biocompatibility testing on aged and unaged devices in compliance with the following standards:

- ISO 11607-1:2019 - *Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems*
- ISTA 3A *International Safe Transit Association: Packaged Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less - March 2018*
- ASTM D4169-22 - *Standard Practice for Performance Testing of Shipping Containers and Systems.*
- *ISO 10993-17:2002 (Ed. 2.0) - Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances*

Human Factors

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 2016)
- IEC 62366-1:2015 AMD1:2020 (Ed. 1.1) - *Medical devices - Part 1: Application of usability engineering to medical devices*
- ANSI/AAMI HE75:2009 (R2018) - Human factors engineering - Design of 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 raise any new or different questions of safety or effectiveness when compared to the predicate device. The results of the design verification and validation testing, including a comprehensive biocompatibility analysis and human factors engineering evaluation, demonstrate that the subject device performed as intended.

8. Conclusion

The performance data fully supports the safety of the subject device and demonstrates the device performs as intended in the specified use conditions. No clinical testing was required or performed to support this application.

There are no new or significantly modified existing risks between the predicate and subject device. The similarity in the predicate and subject device intended use, design and completed performance testing supports a substantially equivalent determination.