December 17, 2020
ACIST Medical Systems, Inc.
Jeff Koll
Sr. Principal Regulatory Affairs Specialist
7905 Fuller Rd
Eden Prairie, Minnesota 55344

Re: K203004
Trade/Device Name: ACIST CVi1 Contrast Delivery System, ACIST CVi Contrast Delivery System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: November 23, 2020
Received: November 24, 2020

Dear Jeff Koll:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Rumi Young
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203004

Device Name
ACIST CVi®1 Contrast Delivery System
ACIST CVi® Contrast Delivery System

Indications for Use *(Describe)*

ACIST CVi®1 Contrast Delivery System

The ACIST CVi®1 Contrast Delivery System is indicated for controlled administration of radiopaque contrast media and saline to human subjects while undergoing angiographic procedures. The CVi®1 Syringe Kits, Manifold Kit and AngioTouch® Hand Controller Kit must be discarded after each patient procedure. The CVi®1 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.

ACIST CVi® Contrast Delivery System

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.

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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Section 2.4 510(k) Summary [21 CFR 807.92]

Submitter's Name and Address	ACIST Medical Systems, Inc. 7905 Fuller Road Eden Prairie, MN 55344 Phone: 952.656.2409 Fax: 952.941.4648
Contact Name and Information	Jeffrey L. Koll Sr. Principal Regulatory Affairs Specialist Phone: 952.656.2409 Fax: 952-941-4648 E-mail: jeff.koll@acistmedical.com
Date Prepared	29 September 2020
Proprietary Name(s)	ACIST CVi®1 Contrast Delivery System ACIST CVi® Contrast Delivery System
Common Name	Contrast Delivery System
Product Code	DXT
Classification	Class II, 21 CFR Part 870.1650, Angiographic injector and syringe
Predicate Device	ACIST CVi®/CVi®1 Contrast Delivery System (K191060)
Device Description	The CVi/CVi1 System is designed to aid the physician in the controlled infusion of radiopaque contrast media. Radiographic imaging devices are used in conjunction with the delivery of contrast media to produce angiograms. Operating environments for the CVi/CVi1 System are catheterization and radiological laboratories. The CVi/CVi1 System contains a software-controlled motor-driven pump that delivers contrast media at a user-determined flow rate and volume via the ACIST provided consumable kits and a hospital provided angiographic patient catheter. The CVi/CVi1 System is also equipped to synchronize with commercially available X-ray imaging systems. The CVi/CVi1 System is used in interventional cardiology, radiology, and vascular surgical procedures. The CVi/CVi1 System device modification that is the subject of this 510k premarket notification is a material component change to the AngioTouch Hand Controller high pressure tubing.

Indications for Use	**ACIST CVi®1 Contrast Delivery System** The ACIST CVi®1 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 **ACIST CVi® Contrast Delivery System** 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.
Substantial Equivalence / Comparison of Technological Characteristics	The proposed AngioTouch Hand Controller modifications to the CVi/CVi1 system includes: • Replacing current braided polyurethane high-pressure tubing with coextruded polyamide/ polyurethane high-pressure tubing. • Replace fixed luers with rotating luers on the high-pressure tubing • Extend shelf life of the modified AngioTouch Hand Controller Kit These modifications do not introduce or raise different questions regarding the safety or effectiveness of the device. The fundamental technological characteristics and principle of operation of the modified device are unchanged from the predicate device. The CVi/CVi1 system with modified AngioTouch Hand Controller is substantially equivalent to the predicate device in intended use, design, performance, and technological characteristics.

Consumable Kit Comparison- AT-P Hand Controller

Characteristic	Predicate Device AngioTouch Hand Controller K191060	Proposed Device AngioTouch Hand Controller (modified) This 510(k)
Intended Use	For controlled administration of radiopaque contrast media and saline to human subjects while undergoing angiographic procedures.	Same
Usability	Single Use	Same
AngioTouch Hand Controller Kit Components	Housings (2) Bladders (2) Twin Tubing High Pressure Tubing	Same
High Pressure Tubing Length	54 inches 65 inches	65 inches
High Pressure Tubing Function	Deliver contrast to patient Deliver saline to patient Provides a hemodynamic pathway from the patient to the hospital's hemodynamic monitoring system	Same
High Pressure Tubing Material	Polyurethane	Polyurethane/Polyamide
Sterilization Method	Ethylene Oxide	Same

Performance Data

The modified device was subjected to bench and biocompatibility testing. Bench testing included burst, functional, life, pressure, bond pull, flow, and durability. Test results demonstrate that the modified device meets specification and performs as intended. No new safety or performance issues were raised during the testing. The modiified device is substantially equivalent to the predicate device.

The following biocompatibility tests were completed:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity

Conclusion

The CVi/CVi1 Contrast Delivery System with modified AngioTouch Hand Controller Kit (AT X) is substantially equivalent in design, performance, and technological characteristics to the predicate device for its intended purpose.