February 16, 2018

ACIST Medical Systems, Inc.
Melissa Sommerfeld
Principal Regulatory Affairs Specialist
7905 Fuller Road
Eden Prairie, Minnesota 55344

Re: K171646
Trade/Device Name: 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: January 16, 2018
Received: January 18, 2018

Dear Melissa Sommerfeld:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Kenneth J. Cavanaugh -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K171646

Device Name
ACIST|CVi® Contrast Delivery System

Indications for Use *(Describe)*
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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K171646 510(k) Summary [21 CFR 807.92]

Submitter's Name and Address	ACIST Medical Systems, Inc. 7905 Fuller Road Eden Prairie, MN 55344 Phone: 952.995.9300 Fax: 952.941.4648
Contact Name and Information	Melissa Sommerfeld Principal Regulatory Affairs Specialist Phone: 952.656.2409 Fax: 952.941.4648 E-mail: melissa.sommerfeld@acistmedical.com
Date Prepared	15 February 2018
Proprietary Name(s)	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
Primary Predicate Device	K991103 ACIST Angiographic Contrast Management Injector System, Model CMS2000
Secondary Predicate Device	K984231 ACIST Angiographic Contrast Management System
Reference Predicate Devices	K010390 ACIST Angiographic Contrast Management Injector System, Model R2000 CMS K040298 ACIST Angiographic Contrast Management System K151048 CT Expres 3D Contrast Media Delivery System, Bottle Spike Type B, Day Set III HP, Patient Set
Device Description	The ACIST | CVi® Contrast Delivery System is designed to aid the physician in the controlled infusion of radiopaque contrast media. The CVi Contrast Delivery System contains a software controlled motor-driven pump that delivers contrast media at a user-determined flow rate and volume. The CVi Contrast Delivery System is used in conjunction with ACIST provided consumable kits: A2000 Syringe Kit, BT2000 Manifold Kit, and the AT-P AngioTouch Hand Controller Kit, and a hospital provided angiographic patient catheter. The CVi Contrast Delivery System is used in interventional cardiology, radiology, and vascular surgical procedures. The operating environments for the CVi Contrast Delivery System are catheterization or radiological laboratories.

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.

Substantial Equivalence / Comparison of Technological Characteristics

The fundamental technological characteristics and principal of operation of the CVi Contrast Delivery System are unchanged from the predicate devices. The CVi Contrast Delivery System contains enhanced safety features for administering contrast media to multiple patients from a single container. The CVi system is substantially equivalent in design, performance, and technological characteristics to the predicate devices for its intended purpose. No new or different questions of safety or effectiveness were raised with the enhancements. A comparison of the predicate and subject devices is provided in Table 1 and 2.

Table 1: Injection System Comparison		
Characteristic	**Predicate Device Injection System CMS2000 K991103**	**Proposed Device Injection System- CVI This 510(k)**
Indications for Use	The ACIST™ CMS-2000 Angiographic Injection System with Contrast Management is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.	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.
Primary System Components	•Injector Head •Power Supply •Control Panel	•Injector Head •Power Supply •Control Panel
Contrast Injection Parameters	•Flow (ml/s): 0.8-40.0 •Volume (ml): 0.8-99.9 •Pressure (psi): 200-1200 •Rise Time (s): 0.0-1.0	•Flow (ml/s): 0.8-40.0 •Volume (ml): 0.8-99.9 •Pressure (psi): 200-1200 •Rise Time (s): 0.0-1.0
Compatible Consumable Kits	•Syringe Kit •Manifold Kit •Hand Controller Kit	•Syringe Kit •Manifold Kit •Hand Controller Kit
Saline Flush	Yes	Yes
Software Controlled Required Syringe Change	No	Yes
Injection Delivery	Variable or Fixed Rate	Variable or Fixed Rate
Equipped with Air Column Detect Sensor	Yes	Yes
X-Ray Imaging Functionality	No	Yes[1]
[1]Cleared in 510(k) K010390		

Table 2: Consumable Kit Comparion- A2000 Syringe

Characteristic	Predicate Device A2000 Syringe K984231	Proposed Device A2000 Syringe This 510(k)
Indications for Use	The ACIST CMS-2000 Angiographic Injection System with Contrast Management is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.	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.
Usability	Up to 5 patient cases	Up to 6 patient cases
Syringe Kit Components	Wiper Wiper Support Rotator Contrast Tubing Contrast O-Ring Contrast Valve Check Ball	Wiper Wiper Support Rotator Contrast Tubing Contrast O-Ring Contrast Valve Check Ball
Disinfecting Cap	No	Yes
Sterilization Method	Gamma Irradiation	Gamma Irradiation

Consumable Kit Comparion- BT2000 Manifold

Characteristic	Predicate Device BT2000 Manifold K984231	Proposed Device BT2000 Manifold This 510(k)
Indications for Use	The ACIST CMS-2000 Angiographic Injection System with Contrast Management is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.	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.
Usability	Single Use	Single Use
Syringe Kit Components	Manifold Shaft Manifold Cap Spring Sealing O-ring Pressure Transducer Valve Trigger	Manifold Shaft Manifold Cap Spring Sealing O-ring Pressure Transducer Valve Trigger
Sterilization Method	Gamma Irradiation	Gamma Irradiation

Consumable Kit Comparion- AT-P Hand Controller

Characteristic	Predicate Device AT-P Hand Controller K040298	Proposed Device AT-P Hand Controller This 510(k)
Indications for Use	The ACIST CMS-2000 Angiographic Injection System with Contrast Management is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.	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.
Usability	Single Use	Single Use
AT-P Hand Controller Kit Components	Housings (2) Bladders (2) Twin Tubing High Pressure Tubing	Housings (2) Bladders (2) Twin Tubing High Pressure Tubing
High Pressure Tubing Length	54 inches 65 inches	54 inches 65 inches
Sterilization Method	Ethylene Oxide	Ethylene Oxide

Performance Data

The CVi Contrast Delivery System was subjected to bench and biocompatibility testing, software validation, system level testing, and human factors testing. Bench testing included burst, functional, life, pressure, bond pull, flow, durability. microbial ingress, and cross contamination. Test results demonstrate that the CVi Contrast Delivery System meets specification and performs as intended. No new safety or performance issues were raised during the testing. The CVi Contrast Delivery System is substantially equivalent to the predicate devices.

The following biocompatibility tests were completed on the CVi Contrast Delivery System:

Cytotoxicity
Sensitization
Irritation
Acute Systemic Toxicity
Material Mediated Pyrogenicity
Hemolysis

Conclusion

The CVi Contrast Delivery System is substantially equivalent in design, performance, and technological characteristics to the predicate devices for its intended purpose.