July 18, 2019

ACIST Medical Systems, Inc.
Matthew Stepanek
Manager, Global Regulatory Affairs
7905 Fuller Road
Eden Prairie, Minnesota 35344

Re: K191060
Trade/Device Name: ACIST | CVi®1 Contrast Delivery System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: April 19, 2019
Received: April 22, 2019

Dear Matthew Stepanek:

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,

Alan Stevens
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)*
K191060

Device Name
ACIST|CVi®1 Contrast Delivery System

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K191060 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	Matthew D. Stepanek Manager, Global Regulatory Affairs Phone: 952-253-4519 Fax: 952-941-4648 E-mail: matt.stepanek@acistmedical.com
Date Prepared	19 April 2019
Proprietary Name(s)	ACIST | CVi®1 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	K171646 ACIST | CVi® Contrast Delivery System

Device Description

The ACIST | CVi1 Contrast Delivery System is designed to aid the physician in the controlled infusion of radiopaque contrast media. The CVi1® Contrast Delivery System contains a software controlled motor-driven pump that delivers contrast media at a user-determined flow rate and volume. The CVi1 Contrast Delivery System is used in conjunction with ACIST provided consumable kits: A1000/A1000V Syringe Kit, BT2000 Manifold Kit, and the AT-P AngioTouch Hand Controller Kit. The current submission introduces the A1000/A1000V Syringe Kit provided in the consumable kits. Changes are also introduced into software and labeling to address single patient use for the consumable kit. The CVi1 Contrast Delivery System is used in interventional cardiology, radiology, and vascular surgical procedures. The operating environments for the CVi1 Contrast Delivery System are catheterization or radiological laboratories. The CVi1 system is used in interventional cardiology, radiology, and vascular surgical procedures. Like the predicate CVi system, the CVi1 system is used in adults and pediatrics patient populations.

Indications for Use

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

Substantial Equivalence / Comparison of Technological Characteristics	The CVi1 system includes modifications to remove functionality for administration of contrast media from the same syringe and imaging bulk pack(IBP) contrast container to multiple patients. This will result in a modified system that will only allow for single patient use of the syringe and contrast media. These modifications do not introduce or raise different questions to the safety or effectiveness of the device. The fundamental technological characteristics and principle of operation of the CVi1 system are unchanged from the predicate device. The CVi1 system is substantially equivalent to the predicate device in intended use, design, performance, and technological characteristics.

Consumable Kit Comparison-Syringe

Characteristic	Predicate Device A2000 Syringe K171646	Proposed Device A1000 and A1000V Syringe This 510(k)	Comparison Analysis
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 five (5) 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|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.	Different
Usability	Up to 5 patient cases	Single Patient Use	Different
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(A1000) or Scepter(A1000V)	Different
Disinfecting Caps and Slide Clamp	Yes	No	Different
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Same

Discussion of similarities and differences:

Similarities: The ACIST|CVi®1 Contrast Delivery System A1000/A1000V Syringes, have the same intended use and fundamental scientific technology as the predicate device. The A1000V Syringe uses a Contrast Valve Check Scepter which is similar to the Contrast Valve Check Ball as found in the A1000 Syringe and predicate device. The purpose and function of the Contrast Valve Check Scepter and Contrast Valve Check Ball are the same. The software for the pump has been updated to remove the ability to reuse the syringe, requiring the user to change syringe after each patient case. The ACIST|CVi®1 System indications for use are similar to the predicate device and result in a modified system that will only allow for single patient use of the syringe with contrast media. These device modifications do not raise any new issues of safety and effectiveness of the device.

Differences: The ACIST|CVi®1 Contrast Delivery System includes modifications to remove functionality for administration of contrast media from the same syringe and IBP contrast container to multiple patients. Specifically, this means the syringe will be indicated for single use and will not require the predicate device's disinfecting caps and slide clamp, as it will be disposed of after each patient use. These modifications do not introduce or raise different questions of safety or effectiveness of the device.

Performance Data	The CVi1 Contrast Delivery System was subjected to bench and biocompatibility testing, human factors and sterility assessment, software verification, and system level testing. Bench testing included burst, functional, life, pressure, bond pull, flow, and durability. Bench performance testing was repeated from the predicate device. The subject device met the same endpoints and criteria as the predicate. Test results demonstrate that the CVi1 Contrast Delivery System meets specification and performs as intended. No new safety or performance issues were raised during the testing. No new critical tasks were identified with the proposed CVi1 when compared with the CVi, thus no additional human factors validation testing is necessary for the CVi1. The CVi1 Contrast Delivery System is substantially equivalent to the predicate device. The A1000V Syringe Kit contains a new contrast valve check scepter compared to the predicate device. To evaluate this change, the following biocompatibility tests were completed on the A1000V Syringe Kit of the CVi1 Contrast Delivery System: Cytotoxicity Sensitization Irritation Acute Systemic Toxicity Material Mediated Pyrogenicity
Conclusion	The CVi1 Contrast Delivery System is substantially equivalent in design, performance, and technological characteristics to the predicate devices for its intended purpose.