June 27, 2019

ACIST Medical Systems, Inc.
Matt Stepanek
Global Manager, Regulatory Affairs
7905 Fuller Rd.
Eden Prairie, Minnesota 55344

Re: K191175
Trade/Device Name: ACIST Kodama Intravascular Ultrasound Catheter, ACIST HDi System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, IYO
Dated: April 30, 2019
Received: May 1, 2019

Dear Matt 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,

Mark Fellman
Assistant Director
DHT2A: Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
OHT2: Office of Cardiovascular 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)*

K191175

Device Name
ACIST Kodama® Intravascular Ultrasound Catheter
ACIST HDi® System

Indications for Use *(Describe)*

The ACIST HDi System is intended to be used for ultrasound examination of coronary and peripheral intravascular pathology. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

The ACIST Kodama Intravascular Ultrasound Catheter is intended for use with the ACIST HDi System.

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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Section 5 510(k) Summary per 21 CFR 807.92

Submitter's Name and Address	ACIST Medical Systems, Inc. 7905 Fuller Road Eden Prairie, MN 55344 USA	
Contact Name and Information	Angela K. Johnson Regulatory Affairs Specialist II ACIST Medical Systems, Inc. 952-253-4571 (office) 952-941-4648 (fax) Angela.Johnson@acistmedical.com	Matthew D. Stepanek Global Regulatory Affairs Manager ACIST Medical Systems, Inc. 952-253-4519 (office) 952-941-4648 (fax) Matt.Stepanek@acistmedical.com
Date Prepared	30 April 2019	
Trade or Proprietary Name	ACIST Kodama® Intravascular Ultrasound Catheter ACIST HDi® System	
Common or Usual Name	Catheter, ultrasound, intravascular System, imaging, pulsed echo, ultrasonic	
Device Classification	Class II	
Product Code, CFR Section	OBJ, 21 870.1200 IYO, 21 892.1560	
Classification Name	Catheter, ultrasound, intravascular System, imaging, pulsed echo, ultrasonic	
Classification Panel	Cardiovascular Radiology	
Predicate Devices	Volcano Eagle Eye Platinum Catheter, K143701 (cleared 26 August 2015) HD-IVUS Ultrasound Imaging System and Kodama Intravascular Ultrasound Catheter, K173063 (cleared 23 October 2017)	
Device Description	The primary function of HDi System is to collect reflected ultrasonic (sound) waves from the Kodama catheter and render an intravascular image on the console touchscreen. The catheter emits sound energy from a transducer at the tip; sound waves reflected from the inner vascular tissues are received from the transducer and sent to the console where a high resolution, cross-sectional image is displayed on the touchscreen in real-time. The main devices are the Console, Patient Interface Module (PIM), Linear Translation System (LTS) (optional), and Kodama Catheter. The console houses hardware and software required to generate the energy used to excite the transducer in the Kodama catheter; it is the center of control and system architecture for how signals are acquired, processed, images constructed and presented, and overall power management and control of the PIM and LTS. The system digitally records case images, provides a review of recorded cases, and provides for the archival of	

	recorded cases onto removable media. The handheld PIM provides the electromechanical interface between the catheter and the console. It also provides the mechanical interface to secure the catheter, as well as the mechanical energy to rotate the catheter's imaging assembly. The LTS device provides automated, controlled linear translation of the catheter by providing mechanical coupling to the PIM and to the catheter's telescoping anchor as the PIM is pulled back along the longitudinal axis. The coupling between the LTS and PIM and LTS to catheter is strictly mechanical. The LTS device allows the user to perform automatic pullbacks and can be controlled via touchscreen buttons on the console or the buttons on the LTS. Manual pullbacks may be performed with or without the LTS, making the use of the LTS optional to the user. The Kodama Catheter emits sound energy from its transducer at the distal tip, which is guided into the coronary and peripheral vasculature. The catheter can be operated at two different frequencies, 40MHz and/or 60MHz, depending on user preference. The catheter design includes an imaging assembly (with transducer, drive cable, coaxial cable, and rotor), sheath assembly (which includes the femoral marker and hydrophilic coating), telescope assembly, and catheter hub assembly. The electrical energy from the catheter is transmitted, via the transmission line embedded in the drive cable, back to the HDi console for signal processing and image reconstruction.
Intended Use/Indications for Use	The ACIST HDi System is intended to be used for ultrasound examination of coronary and peripheral intravascular pathology. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures. The ACIST Kodama Intravascular Ultrasound Catheter is intended for use with the ACIST HDi System.
Comparison of Technological Characteristics to Predicate	The proposed devices are substantially equivalent to the predicate devices (K143701 & K173063) based on the same indications for use as described in the labeling, the same fundamental scientific technology, safety, and performance testing. The system contains similar components and similar accessories when compared to the predicate device. The Kodama Catheter and HDi System are substantially equivalent to the predicate devices in intended use, design, performance, and technological characteristics.
Performance Data	The Kodama Catheter and HDi System was subjected to bench testing, including trackability and deliverability (including insertion/retraction force, cross/re-cross force, kink resistance, and torque strength), runtime, non-uniform rotational distortion (NURD) and buckling force. Where applicable, testing was leveraged from the predicate device to support this submission. Test results demonstrate that the Kodama Catheter and HDi System meet specifications and perform as intended. No new safety or performance issues were raised during the testing. The Kodama Catheter and HDi System are substantially equivalent to the predicate devices.
Summary of Clinical Testing – Animal	An animal study was conducted by ACIST Medical Systems in a laboratory environment, using a porcine model, to confirm the HDi System and Kodama Catheter imaging capabilities in the peripheral vessels and to collect supporting evidence regarding use of the HDi System and Kodama Catheter in the peripheral vessels. The physician also provided evaluation on the usability of Kodama catheter in peripheral arteries, such as catheter set-up,

	delivery and retraction. Test results demonstrate that the device meets specification and performs as intended. Results of the testing do not introduce or raise different questions regarding the safety or effectiveness of the device.
Substantial Equivalence / Comparison of Technologic Characteristics	The HDi System and Kodama Catheter have identical design components to the currently marketed HDi System and Kodama Catheter, cleared under K173063. There are no device modifications associated with the proposed expanded indications for use. The proposed Kodama Catheter and predicate catheter, Volcano Eagle Eye Platinum, are both intended for ultrasound imaging of coronary and peripheral vasculature by providing cross-sectional images of vessel lumen, vessel wall morphology, and devices (e.g., stents) at or near the surface of the vessel wall. Both the Kodama Catheter and predicate catheter have similar design characteristics, including a tapered soft tip, internal lumen, hydrophilic coating, radiopaque markers, compatibility with guidewires up to 0.014”, similar working lengths, and similar ultrasound transducer technology. The proposed HDi System and Kodama Catheter are substantially equivalent to the predicate devices in intended use, design, performance, and technological characteristics.
Conclusion	Based on the same indications for use, same fundamental technology, and safety and performance testing, the HDi System and the Kodama Catheter have been shown to be appropriate for their intended use and are considered to be substantially equivalent to the predicate devices submitted in K143701 and K173063.