October 23, 2017

ACIST Medical Systems, Inc.
Amber Luker
Senior Regulatory Affairs Specialist
7905 Fuller Road
Eden Prairie, Minnesota 55344

Re: K173063
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: September 28, 2017
Received: September 29, 2017

Dear Amber Luker:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for 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)*
K173063

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

Indications for Use *(Describe)*
The ACIST HDi System is intended to be used for the intravascular ultrasound imaging assessment of coronary artery disease. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

The ACIST Kodama Intravascular Ultrasound Catheter is a medical device for use by or on the order of a physician and is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

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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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	Amber R. Luker, RAC Senior Regulatory Affairs Specialist ACIST Medical Systems, Inc. 952-995-9317 (office) 952-941-4648 (fax) amber.luker@acistmedical.com
Date Prepared	28 September 2017
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	HD-IVUS Ultrasound Imaging System, K122878 (cleared 11 January 2013) Kodama Intravascular Ultrasound Catheter, K113008 (cleared 14 June 2012)
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 arteries of the heart. 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 the intravascular ultrasound imaging assessment of coronary artery disease. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures. The ACIST Kodama Intravascular Ultrasound Catheter is a medical device for use by or on the order of a physician and is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.
Comparison of Technological Characteristics to Predicate	The proposed devices are substantially equivalent to the predicate devices (K113008 & K122878) 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.
Non-Clinical Tests in Support of Substantial Equivalence	The Medical Advisory Board supports the proposed changes to the labeling contraindications and adverse events. Cumulative changes are supported by bench testing, operating environment testing, packaging verification, software verification, electrical safety testing (IEC 60601-1), electromagnetic compatibility testing (IEC 60601-1-2), and biocompatibility testing. The results of these tests provide reasonable assurance that the proposed devices have been designed and tested to assure conformance to the requirements for their intended use. No new safety or performance issues were raised during the testing and, therefore, the HDi System and Kodama Catheter may be considered substantially equivalent to the predicate devices.
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 K122878 and K113008.