March 20, 2020

ACIST Medical Systems, Inc.
Angela Johnson
Regulatory Affairs Specialist II
7905 Fuller Rd
Eden Prairie, Minnesota 55344

Re: K193183
Trade/Device Name: ACIST HDi System, ACIST Kodama Intravascular Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, IYO
Dated: February 18, 2020
Received: February 20, 2020

Dear Angela Johnson:

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)*
K193183

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

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.

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Section 1 510(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
Date Prepared	18 February 2020
Trade or Proprietary Name	ACIST HDi® System ACIST Kodama® Intravascular Ultrasound Catheter
Common or Usual Name	System, imaging, pulsed echo, ultrasonic Catheter, ultrasound, intravascular
Device Classification	Class II
Product Code, CFR Section	IYO, 21 892.1560 OBJ, 21 870.1200
Classification Name	System, imaging, pulsed echo, ultrasonic Catheter, ultrasound, intravascular
Classification Panel	Radiology Cardiovascular
Predicate Devices	HD-IVUS Ultrasound Imaging System and Kodama Catheter, K191175 (cleared 27 June 2019)
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. The electrical energy from the catheter is transmitted, via the coaxial cable 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 HDi System software has been modified to extend the field of view for larger peripheral vessels. The predicate device provides the option to use standard definition (40MHz) or high definition (60MHz) imaging with a 6, 8, and 10 mm field of view. The proposed device adds the ability to image in 12, 16, and 20 mm field of view and automatically selects the highest definition available for the field of view selected by the user. The HDi system contains identical hardware components and accessories when compared to the predicate device. No changes were made to the Kodama Catheter associated with this change. The Kodama Catheter and HDi System are substantially equivalent to the predicate devices (K191175) in intended use, design, performance, and technological characteristics.
Substantial Equivalence and Summary of Studies	No device modifications were made to the Kodama Catheter or HDi System hardware and accessories for this change. Testing was limited to the safety and effectiveness of the HDi System software and firmware. The HDi System was subjected to design verification and validation activities, including software and system level verification testing, end user software validation, and animal study validation, to ensure the software modifications did not affect the safety and effectiveness of the device. Design verification testing included verifying all testing for the application software and FPGA firmware. Specifically, the following items were directly correlated to the extended field of view change and were verified: • The Acquire screen is displayed during Imaging, Recording and Pullback and it has appropriate functional elements, including the new "Diameter" button. • The Zoom/Decimation function allows the image to be magnified to the specified depth range in the extended field of view

	• The time gain compensation (TGC) control curve is controlled dynamically by the Diameter selection and covers the appropriate anatomical depth range. All software and system verification testing were executed with passing results. Design validation testing was conducted to ensure users can utilize the new software features and interpret the resulting images correctly and that there were not new use errors identified. Primary changes observed by the user are Graphical User Interface (GUI) changes to the "diameter" selection feature that sets the system field of view range and frequency. All design validation testing was executed with passing results. Animal study validation testing was conducted to demonstrate that the IVUS image quality generated by the HDi System with the modified system software is clinically useful at extended field of view diameters (12, 16, and 20 mm) and is equivalent to the current commercially available software within current field of view (6, 8, and 10 mm). Physician assessment confirmed: • IVUS images generated with the modified system software at 10mm field of view are substantially equivalent to IVUS images generated by current system software at 10 mm field of view. • All IVUS images generated by the modified system software at 20 mm field of view are clinically useful, especially for vessel lumen measurement and determining stent strut location. • All IVUS images generated by the modified systems software which measured the lumen at 20 mm field of view do not show any differences between 1.0 mm/s pullback speed (30 f/s) and 10.0 mm/s pullback speed (60 f/s). Test results demonstrate the HDi System met the established performance specifications and performs as intended. No new safety or performance issues were raised during the testing. One new use related risk was identified due to changes in the software user interface selection options; however, the overall risk profile of the device has not changed. Results of design verification and validation testing on the HDi System demonstrate that the device is as safe, as effective, and performs equivalently to the predicate device. Software documentation for a Moderate Level of Concern software per FDA's Guidance document "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" (issued May 11, 2005) is included in this premarket notification.