Class 1 Device Recall ACIST Kodama Intravascular Ultrasound Catheter

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See Related Information[22]

Date Initiated by Firm	January 22, 2021
Date Posted	March 04, 2021
Recall Status[1]	Open[3], Classified
Recall Number	Z-1161-2021
Recall Event ID	87254[23]
510(K)Number	K193183[24]
Product Classification	Catheter, ultrasound, intravascular[25] - **Product Code** OBJ[26]
Product	ACIST Kodama Intravascular Ultrasound Catheter The Kodama Intravascular Ultrasound Catheter is a component of the ACIST HDi System. 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.
Code Information	Model Number: 017788, 018125 (Japan only); Lot codes: 00233370 (100 units), 00233371 (90 units), 00233372 (100 units), 00233373 (100 units), 00233374 (100 units), 00233380 (100 units), 00233384 (60 units), 00233385 (100 units), 00233393 (100 units), 00233394 (100 units), 00237604 (35 units), 00237613 (100 units), 03012517 (100 units)
Recalling Firm/ Manufacturer	Acist Medical Systems 7905 Fuller Rd Eden Prairie MN 55344-2137
For Additional	Kristen Knox

Information Contact	952-374-9083
Manufacturer Reason for Recall	Test results from the manufacturing line found a piece of damaged o-ring in an unexpected section of the catheter. Further testing indicated that pieces (>200 micron) of damaged o-ring had the potential to be flushed out of the catheter. ACIST is confirming the source of the failure mode to assure the quality and reliability of the Kodama catheter. There have been no related field reports related to this incident, nor any evidence or report of patient injury or adverse health consequence.
FDA Determined Cause [2]	Under Investigation by firm
Action	The firm, ACIST, sent an, "URGENT: MEDICAL DEVICE RECALL" letter and response form dated Jan 22, 2021 to customers on Jan. 22, 2021. The letter describe the product, problem and actions to be taken. The customers were instructed to do the following: to complete all of the steps outlined below and return the completed Recall Response Form to Stericycle by e-mail: acistmedical8961@stericycle.com or fax to 877-576-9366. 1. Check your inventory of Kodama HD-IVUS Catheter 2. Record quantities of each lot in the Response Form 3. Remove the affected lots from your inventory. 4. Use the enclosed, prepaid return label to return your affected product including a copy of the response form with the product. If you need additional labels, please contact Stericycle at 877-576-9382. If you have received any reports of illness, injury or other health consequence related to the use of product please contact Customer Support: Customer.Support@acistmedical.com Please forward this notice to those who need to be aware within your organization. If you have any further questions or concerns, please contact Stericycle at 877-576-9382.
Quantity in Commerce	1185 units
Distribution	Worldwide - US Nationwide Distribution in the states of AL, AR, CA, CO, FL, IL, KS, KY, LA, MD, MI, MO, NC, NJ, NY, OK, PA, RI, TN; In the countries of India, Italy, Japan, Poland, and United Arab Emirates.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database	510(K)s with Product Code = OBJ and Original Applicant = ACIST Medical Systems, Inc.[29]

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