FDA

Class 2 Device Recall UST5550R Ultrasound Transducer,

See Related Information[22]

Date Initiated by Firm	October 20, 2017
Create Date	March 01, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0816-2018
Recall Event ID	79160[23]
510(K)Number	K152126[24]
Product Classification	Transducer, ultrasonic, diagnostic[25] - **Product Code** ITX[26]
Product	Ultrasound Transducer, Model Number: UST-5550-R, is used in conjunction with a diagnostic ultrasound system evaluation during robotic and non-robotic intra-operative and laparoscopic procedures.
Code Information	17, 21, 32, 37, 38, 39, 41, 43, 45, 46, 48, 57, 58, 59, 61, 63, 64, 69, 73, 77, 78, 81, 82, 86, 87, 92, 96, 97, 99, 107, 108, 109, 114, 115, 116, 118, 120, 121, 122, 126, 129, 130, 132, 135, 139, 140, 141, 143, 144, 147, 148, 151, 155.
Recalling Firm/ Manufacturer	Hitachi Medical Systems America Inc 1959 Summit Commerce Park Twinsburg OH 44087-2371
For Additional Information Contact	Douglas J. Thistlethwaite 330-425-1313 Ext. 3720
Manufacturer Reason for Recall	The ultrasound probe may not have adequate protection against electrical shock hazards.
FDA Determined Cause [2]	Mixed-up of materials/components
Action	Hitachi must recall the lot of UST-5550-R Transducers from S/N 1 to S/N 155. If you have a serial number in this range, please contact Hitachi Service at (800) 800-4925 to schedule the recall. Hitachi Sales will contact you regarding the options for a replacement transducer.
Quantity in Commerce	55
Distribution	Distributed in 21 states: AR, AZ, CA, CO, FL, GA, IA, IL, IN, MA, MO, NC, NY, OK, OR, PA, SC, TX, VA, WA, WV.
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.