### Class 2 Device Recall UST5550R Ultrasound Transducer

#### Date Initiated by Firm
October 20, 2017

#### Create Date
March 01, 2018

#### Recall Status
Open, Classified

#### Recall Number
Z-0816-2018

#### Recall Event ID
79160^23

#### 510(K)Number
K15212^24

#### Product Classification
Transducer, ultrasonic, diagnostic — Product Code ITX

#### 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, 131, 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. Thistleton
330-425-1313 Ext. 3720

#### Manufacturer Reason for Recall
The ultrasound probe may not have adequate protection against electrical shock hazards.

#### FDA Determined Cause
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

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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.

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.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=161462 3/7/2018