Class 2 Device Recall Synapse PACS

Date Initiated by Firm  
March 02, 2021

Create Date  
April 02, 2021

Recall Status  
Open, Classified

Recall Number  
Z-1348-2021

Recall Event ID  
87579

510(K)Number  
K160108

Product Classification  
System, image processing, radiological

Product  
Synapse PACS - Radiological Image Processing System - Product Usage: intended for use, as a web based application, on an off-the-shelf PC meeting or exceeding minimum specifications and networked with FUJIFILM Synapse PACS Software (Server).

Code Information  
Software version: 5.1 to 5.7.200

Recalling Firm/Manufacturer  
Fujifilm Medical Systems U.S.A., Inc.  
81 Hartwell Ave Ste 300  
Lexington MA 02421-3160

For Additional Information Contact  
Jeffrey Wan  
201-675-8947

Manufacturer Reason for Recall  
The wrong patient information may be displayed in the viewer or PowerJacket.

FDA Determined Cause  
Software design

Action  
On March 2, 2021, FUJIFILM Medical Systems U.S.A., Inc. (FUJIFILM) issued an Urgent Medical Device Recall notice for the voluntary recall of Synapse PACS versions 5.1 and higher via certified mail.

Distribution  
Worldwide distribution - US Nationwide distribution including in the states of AZ, CA, CO, CT, DC, FL, GA, HI, IA, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, VA, VT, WA, WI, WV, WY, and the countries of United Arab Emirates, Angola, Argentina, Austria, Australia, Belgium, Bermuda, Brazil, Canada, Switzerland, Chile, Colombia, Costa Rica, Czechia, Germany, Spain, Finland, France, United Kingdom, Greece, Guatemala, Hong Kong, Indonesia, Israel, India, Italy, Jordan, Japan, Kuwait, Malta, Mexico, Malaysia, Netherlands, Peru, Philippines, Pakistan, Poland, Portugal, Russia, Saudi Arabia, Singapore, Slovenia, Slovakia, El Salvador, Thailand, Turkey, Uruguay, South Africa, Zimbabwe.

Total Product Life Cycle  
TPLC Device Report
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.

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

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 = LLZ and Original Applicant = FUJIFILM MEDICAL SYSTEMS U.S.A., INC.
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)

U.S. Department of Health & Human Services

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4. http://www.fda.gov/MedicalDevices/default.htm
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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
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23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=87579
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K160108
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26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LLZ
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=LLZ
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start_search=1&productcode=LLZ&knumber=&applicant=FUJIFILM%20MEDICAL%20SYSTEMS%20U%2ES%2EA%2E%2C%20INC%2E