Class 2 Device Recall Synapse PACS

Class 2 Device Recall Synapse PACS

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Date Initiated by Firm	March 02, 2021
Create Date	April 02, 2021
Recall Status[1]	Open[3], Classified
Recall Number	Z-1348-2021
Recall Event ID	87579[23]
510(K)Number	K160108[24]
Product Classification	System, image processing, radiological[25] - **Product Code** LLZ[26]
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 [2]	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.
Quantity in Commerce	839 systems
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[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 = LLZ and Original Applicant = FUJIFILM MEDICAL SYSTEMS U.S.A., INC.[29]

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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=87579
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K160108
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LLZ
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LLZ
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=LLZ
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=LLZ&knumber=&applicant=FUJIFILM%20MEDICAL%20SYSTEMS%20U%2ES%2EA%2E%2C%20INC%2E

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19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=87579
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K160108
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LLZ
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LLZ
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=LLZ
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=LLZ&knumber=&applicant=FUJIFILM%20MEDICAL%20SYSTEMS%20U%2ES%2EA%2E%2C%20INC%2E