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## Class 2 Device Recall Synapse PACS



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### Class 2 Device Recall Synapse PACS



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<b>Date Initiated by Firm</b>	March 02, 2021
<b>Create Date</b>	April 02, 2021
<b>Recall Status</b> <sup>1</sup>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-1348-2021
<b>Recall Event ID</b>	<a href="#">87579</a> <sup>23</sup>
<b>510(K)Number</b>	<a href="#">K160108</a> <sup>24</sup>
<b>Product Classification</b>	<a href="#">System, image processing, radiological</a> <sup>25</sup> - <a href="#">Product Code LLZ</a> <sup>26</sup>
<b>Product</b>	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).
<b>Code Information</b>	Software version: 5.1 to 5.7.200
<b>Recalling Firm/ Manufacturer</b>	Fujifilm Medical Systems U.S.A., Inc. 81 Hartwell Ave Ste 300 Lexington MA 02421-3160
<b>For Additional Information Contact</b>	Jeffrey Wan 201-675-8947
<b>Manufacturer Reason for Recall</b>	The wrong patient information may be displayed in the viewer or PowerJacket.
<b>FDA Determined Cause</b> <sup>2</sup>	Software design
<b>Action</b>	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.
<b>Quantity in Commerce</b>	839 systems
<b>Distribution</b>	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.
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>27</sup>

<sup>1</sup> 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](#)<sup>28</sup>.

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

<sup>3</sup> 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.](#)<sup>29</sup>

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