


[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

Class 2 Device Recall uCT 780


[510\(k\)](#)⁷ [De Novo](#)⁸ [Registration & Listing](#)⁹ [Adverse Events](#)¹⁰ [Recalls](#)¹¹ [PMA](#)¹² [HDE](#)¹³ [Classification](#)¹⁴ [Standards](#)¹⁵
[CFR Title 21](#)¹⁶ [Radiation-Emitting Products](#)¹⁷ [X-Ray Assembler](#)¹⁸ [Medsun Reports](#)¹⁹ [CLIA](#)²⁰ [TPLC](#)²¹
[New Search](#)
[Back to Search Results](#)

Class 2 Device Recall uCT 780



Date Initiated by Firm	August 11, 2026
Date Posted	September 25, 2026
Recall Status ¹	Open ³ , Classified
Recall Number	Z-3280-2026
Recall Event ID	99731 ²³
510(K)Number	K230162 ²⁴ K241079 ²⁵ K253173 ²⁶ K172135 ²⁷
Product Classification	System, x-ray, tomography, computed ²⁸ - Product Code JAK ²⁹
Product	Computed Tomography X-ray System, Model: uCT 780 with software
Code Information	UDI-DI: 06971576831050. Serial Number/Software: 684001/R001.17.6.1607336-Re3100SP4, 684002/R001.17.6.1607336-Re3100SP4, 684003/R003.8.4.1810621-Re3300SP1H1_P3, 684004/R003.8.4.1810621-Re3300SP1H1_P3, 684005/R003.8.4.1810621-Re3300SP1H1_P3, 684006/R003.8.4.1810621-Re3300SP1H1_P3, 684007/R003.8.4.1810621-Re3300SP1H1_P3, 684008/R003.8.4.1810621-Re3300SP1H1_P3, 684009/R003.8.4.1810621-Re3300SP1H1_P3, 684010/R003.8.4.1810621-Re3300SP1H1_P3, 684011/R003.8.4.1810621-Re3300SP1H1_P3, 684012/R003.9.0.1776134-Re-3300SP2, 684013/R003.11.0.1897081-Re3310SP1, 684014/R003.11.0.1897081-Re3310SP1
FEI Number	3011015597
Recalling Firm/ Manufacturer	Shanghai United Imaging Healthcare Co., Ltd. No. 2258 Chengbei Rd, Jiading Ind. Shanghai China
Manufacturer Reason for Recall	Positron emission tomography and computed tomography x-ray systems have a software problem when Split or Local function is enabled, and multiple RIS exams are merged into a single study, that prevents patient images from being visible on the Patient Administration interface, which may result in the need for rescans.
FDA Determined Cause ²	Software design
Action	On 8/11/2026, correction notices were emailed to customers informing them that software will be released to resolve the software problem. Customers were asked to do the following: When using the Study Split function, follow the requirements below: 1) Temporarily disable the "Study Split" function. Navigate to the system configuration interface and uncheck the "Auto Study Split" option. 2) If the "Study Split" function is clinically necessary, open the system configuration interface and select "Split on PACS" instead of "Split on Local". 3) When "Auto study split" is checked, ensure that PACS (Picture Archiving and Communication System) is configured on site and auto-archive is enabled. 4) If images are found to be missing on the PA interface, immediately verify whether the corresponding image data exists in the PACS. a) If images exist in PACS: They can be retrieved from PACS for review. b) If images do not exist in PACS: Contact the firm's service engineer for assistance.

For further questions, contact firm service engineer or call firm Customer Contact Center at (855) 221-1552 or 832-699-2799

Quantity in Commerce 14

Distribution US Nationwide distribution in the states of CA, PR, UT, WV, ND, NE, NC, TX, ID, LA, MT, FL, CO, IN, KY, AL, OH, MI, IA, MO, NY, NV, TN, WV, SC, WI, IL, MS, MA, NJ.

Total Product Life Cycle [TPLC Device Report](#)³⁰

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](#)³¹.

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 = JAK](#)³²

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <https://www.fda.gov/>
4. <https://www.fda.gov/Medical-Devices>
5. <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
8. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>
9. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
10. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
11. </scripts/cdrh/cfdocs/cfRES/res.cfm>
12. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>
13. </scripts/cdrh/cfdocs/cfHDE/hde.cfm>
14. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
15. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
16. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
19. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
20. </scripts/cdrh/cfdocs/cfClaia/Search.cfm>
21. </scripts/cdrh/cfdocs/cfTPLC/tplc.cfm>
22. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports>
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=99731
24. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K230162>
25. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241079>
26. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K253173>
27. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K172135>
28. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JAK>
29. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JAK>
30. </scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=JAK>
31. <https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall>
32. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=JAK&number=&applicant=Shanghai%20United%20Imaging%20Healthcare%20Co%2E%2C%20Ltd%2E

Page Last Updated: 09/28/2026

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [العربية](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [فارسی](#) | [English](#)

[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA](#) [No FEAR Act](#) [Nondiscrimination](#) [Website Policies](#) / [Privacy](#)



U.S. Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
[Contact FDA](#)



[For Government For Press](#)

[Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy](#)



U.S. Department of **Health & Human Services**

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <https://www.fda.gov/>
4. <https://www.fda.gov/Medical-Devices>
5. <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
8. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>
9. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
10. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
11. </scripts/cdrh/cfdocs/cfRES/res.cfm>
12. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>
13. </scripts/cdrh/cfdocs/cfHDE/hde.cfm>
14. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
15. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
16. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
19. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
20. </scripts/cdrh/cfdocs/cfCla/Search.cfm>
21. </scripts/cdrh/cfdocs/cfTPLC/tplc.cfm>
22. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports>
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=99731
24. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K230162>
25. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241079>
26. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K253173>
27. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K172135>
28. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JAK>
29. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JAK>
30. </scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=JAK>
31. <https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall>
32. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=JAK&knumber=&applicant=Shanghai%20United%20Imaging%20Healthcare%20Co%2E%2C%20Ltd%2E