Class 2 Device Recall Alphenix INFX8000C/B5

See Related Information[22]

Date Initiated by Firm	August 26, 2026
Date Posted	October 07, 2026
Recall Status[1]	Open[3], Classified
Recall Number	Z-0108-2027
Recall Event ID	99817[23]
510(K)Number	K210900[24]
Product Classification	Interventional fluoroscopic x-ray system[25] - **Product Code** OWB[26]
Product	Alphenix INFX-8000C/B5
Code Information	Serial no. B5F2532011/UDI: 4987670100192
FEI Number	2020563
Recalling Firm/ Manufacturer	Canon Medical System, USA, INC. 2441 Michelle Dr Tustin CA 92780-7047
For Additional Information Contact	Orlando Tadeo 714-730-5000
Manufacturer Reason for Recall	Loosening of the bolts securing the longitudinal movement mechanism may cause the tabletop to shift, resulting in [positional/imaging/patient] misalignment and a longitudinal motion error
FDA Determined Cause [2]	Process control
Action	On August 26, 2026, Canon Medical Systems USA, Inc. issued a Urgent: Medical Device Correction notification to affected consignees via mail. Canon ask consignees to take the following actions: 1. Should this problem occur before inspection of the tightening of the bolt(s) is implemented on your system, please stop using the device and call your service representative. 2. Additionally, it is strongly requested that you share the contents of this letter with all users as well as clinical engineering or biomedical group at your facility. 3. A representative of Canon Medical Systems USA will contact you to schedule a time to inspect the tightening and properly fixing of the bolt(s) to correct this issue with your system(s). 4. If you have any questions regarding this matter, please contact your service representative contact our InTouch team at (800) 521-1968 or by email at intouchdispatch@us.medical.canon.

	5. Canon respectfully requests that the attached form be completed and returned via email to fieldcorrections@us.medical.canon.
Quantity in Commerce	1 unit
Distribution	US Nationwide distribution in the state of ID.
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 = OWB[29]

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