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Class 2 Device Recall Alphenix



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Class 2 Device Recall Alphenix



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Date Initiated by Firm	August 04, 2026
Date Posted	August 25, 2026
Recall Status ¹	Open ³ , Classified
Recall Number	Z-3014-2026
Recall Event ID	99222 ²³
510(K)Number	K182415 ²⁴ K203551 ²⁵ K210900 ²⁶
Product Classification	Interventional fluoroscopic x-ray system ²⁷ - Product Code QWB ²⁸
Product	Alphenix Models INFX-8000C INFX-8000F INFX-8000V This device is a digital radiography/fluoroscopy system used in a diagnostic and interventional angiography configuration. The system is indicated for use in diagnostic and angiographic procedures for blood vessels in the heart, brain, abdomen and lower extremities.
Code Information	Model Number: INFX-8000C/B3 UDI code: Pending SID Number:30101165 Serial Number: B3E2422005 Model Number: INFX-8000F/SG UDI code: Pending SID Number: 30093711 Serial Number: SGC2412001 Model Number: INFX-8000V/SZ UDI code: Pending SID Number: 30029686 Serial Number: SZA2422001 SID Number: 79000002 Serial Number:SZA2442004 Model Number: INFX-8000V/SX UDI code: Pending SID Number: 30049491 Serial Number: SXA2432001 SID Number: 30100053 Serial Number: SXA2432002 Model Number: INFX-8000V/B9 UDI code: Pending SID Number: 30059175 Serial Number: B9F2412001 Model Number: INFX-8000V/ST UDI code: Pending SID Number: 30059180 Serial Number: STA2412001 Model Number: INFX-8000V/SZ UDI code: Pending SID Number: 30095017 Serial Number: SZA2432003 SID Number: 30097052 Serial Number: SZA2422002

FEI Number	2020563
Recalling Firm/ Manufacturer	Canon Medical System, USA, INC. 2441 Michelle Dr Tustin CA 92780-7047
For Additional Information Contact	Orlando Tadeo 714-483-1551
Manufacturer Reason for Recall	Due to the fixing screws of ceiling movement gear in ceiling suspended arm that are part of the X-ray interventional systems may become loose.
FDA Determined Cause ²	Process control
Action	On 08/04/2026, an "URGENT: MEDICAL DEVICE CORRECTION" letter was sent via email informing customers that, It has been found there is a possibility that the fixing screws of ceiling movement gear in ceiling suspended arm that are part of the X-ray interventional systems may become loose. Indications that the screws have loosened are abnormal noises and sensor errors from the ceiling mounted C-arm. Customers are instructed to: Should the suspended device make an abnormal noise, or a sensor error is displayed before the corrective action is implemented on your system, please stop using the device and call your local Canon Service Team. 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. A representative of Canon Medical Systems USA will contact customers to schedule a time to check for the tightening and proper attachment of the fixing screws to correct this issue your system(s). For Questions - contact your service representative contact the InTouch team at intouchdispatch@us.medical.canon.
Quantity in Commerce	10 systems
Distribution	U.S. Nationwide distribution in the states of CA, GA, MN, NC, NV, PA, OH, and TX.
Total Product Life Cycle	TPLC Device Report ²⁹

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](#)³⁰.

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 = QWB](#)³¹

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Page Last Updated: 08/31/2026

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