California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Calyxo, Inc. CVAC Aspiration System

Recall Date	Product Description	Recalling Firm	Recall Reason
03/21/2025	CVAC Aspiration System REF: CVC127020-1 User Manual: L00018 Intended for endoscopic examination/treatment of urinary tract and kidney interior.	Calyxo, Inc.	Aspiration system, for endoscopic examination/treatment of urinary tract and kidney interior, to have labeling update adding additional instructions, for patients with high viscosity fluid in the kidney, not to continue providing fluid inflow in the presence of unresolved slow or absent fluid outflow because this can create intrarenal pressure imbalance, and lead to excessive intrarenal pressure.

Recall Class	Product Identification	Distribution	Affected Dates
I	REF: CVC127020-1 UDI-DI: 00860005357710 User Manual: L00018 Revision: Rev C	11,246 units nationwide	February and prior

For additional information, please visit the FDA Website.