California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Merit Medical Systems Inc. Recalls Prelude SNAP (Introducer Catheter kit)

Recall Date	Product Description	Recalling Firm	Recall Reason
8/21/2024	Various Merit Medical convenience kits that contain recalled Jiangsu Shenli Medical Production Co. Ltd. Syringes. Prelude SNAP (Introducer Catheter kit), REF: For the introduction of various types of pacing leads and catheters to the heart and coronary venous system.	Merit Medical Systems Inc. South Jordan, UT	Medical convenience kits contain plastic syringes affected by the FDA Safety Alert issued on March 19, 2024. Leaks, breakage, and/ other quality issues have been identified that may pose a risk to patient health.

Recall Class	Product Identification	Distribution	Affected Dates
II	Catalog Number/UDI-DI: PLS-1006/A/00884450467954, PLS-1007/A/00884450467985, PLS-1008/A/00884450467992, PLS-1009.5/A/00884450468036, PLS-1009/A/00884450468012, PLS-2508/A/00884450468111, PLS-2509/A/00884450468128, PLSX-1007/A/00884450489567	800 units in California	August 2024 and prior.

For additional information, please visit the FDA Website.