

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Stryker Sustainability Solutions Recalls Disposable 5 Lead Cable And Lead Wire System Package

Recall Date	Product Description	Recalling Firm	Recall Reason
08/28/2024	Disposable 5 Lead Cable and Lead Wire System, 50 inches, REF: LW-309DS50/5A.	Stryker Sustainability Solutions Tempe, AZ	Disposable 5 lead cable and lead wire system package that should contain lead systems, lead telemetry systems and a dual connect cable, may in fact contain, different ECG Leads, which are not approved for reprocessing, but that may have been reprocessed, which may lead to devices not performing as intended.

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI-DI/Lot Numbers: 07613327483918/0000111423 – 13325718	12500 units in California	August 2024 and prior.

For additional information, please visit the [FDA Website](https://www.fda.gov).