

## California Device Recall Information Sheet

### Food and Drug Branch – Device Recalls

Elucent Medical Inc. Recalls EnVisio Patient Pad Transition Cushion

Recall Date	Product Description	Recalling Firm	Recall Reason
01/06/2025	EnVisio Patient Pad Transition Cushion, Model/Catalog Number: ENVISIO-SYS Product Description: The EnVisio Patient Pad Transition Cushion is a component of the EnVisio Navigation System which is a medical device that detects the presence of the SmartClip Soft Tissue Marker(s) and provides real-time three-dimensional navigation during surgery.	Elucent Medical Inc.	There is a potential safety risk caused by physical disassociation of the back section from the bed frame of Skytron model series 3600, 6500, 6600 and 6700 operating room beds when used with the EnVisio Navigation System.

Recall Class	Product Identification	Distribution	Affected Dates
II	Lot Code: All EnVisio Patient Pad Transition Cushions REF: ENVISIO-CUSHION	7 affected EnVisio Patient Pad Transition Cushions have been distributed to California. All have been recovered and replaced with a newly designed Patient Pad Transition Cushion.	January 2025 and Prior

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