

## California Device Recall Information Sheet

### Food and Drug Branch – Device Recalls

Intelerad Medical Systems Incorporated IntelePACS (Image Fusion Module) - InteleViewer

Recall Date	Product Description	Recalling Firm	Recall Reason
02/21/2025	IntelePACS (Image Fusion Module) - InteleViewer	Intelerad Medical Systems Incorporated	A software application that receives digital images and data from various sources has a bug in specific software versions that will calculate the Standard Uptake Value (SUV) incorrectly for PET/CT studies acquired on the days of Daylight Savings Time (DST); only on dates in which DST transition occurs; all other dates are unaffected. An incorrect SUV may lead to an incorrect diagnosis.

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI-DI: B228INTELEPACS0  Device Versions: 5-6-1-P23 and later	13 units in California	February and prior

For additional information, please visit the [FDA Website](#).