California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Medicrea International UNiD" Adaptive Spine Intelligence UNiD Spine Analyzer

Recall Date	Product Description	Recalling Firm	Recall Reason
02/06/2025	UNiD" Adaptive Spine Intelligence UNiD Spine Analyzer Two cloud-based software applications within UNiD Adaptive Spine Intelligence (ASI): the UNiD HUB and the UNiD Spine Analyzer. The UNiD HUB cloud-based software is a healthcare application to receive, transfer, display, store data needed for planning a spine surgery or for post-operative follow-up (patient information, X-ray image and recommendations for planning). The UNiD Spine Analyzer cloud based software is a healthcare application intended for assisting healthcare professionals in viewing and measuring images as well as planning spine surgeries.	Medicrea International	Due to software anomalies that may impact on rod planning specifically, certain optional surgical parameters may have had errors that resulted i incorrect calculations displayed on system. Impacted parameters includes the following: Roussouly Classification, Real Lumbar Lordosis and Real Thoracic Kyphosis, Barrey Ratio, and Lenke Classification.

Recall Class	Product Identification	Distribution	Affected Dates
II	UNiD HUB is not a medical device and thus does not have a	1,548 users nationwide	December and prior

	CFN or GTIN code. UNiD Spine Analyzer Product Number: SW3002 UDI-DI code: 03613720286929 No lot numbers		

For additional information, please visit the FDA Website.

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