California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Mint Medical GmbH mint Lesion

Recall Date	Product Description	Recalling Firm	Recall Reason
12/19/2024	mint Lesion Software Versions: 3.9.0 through 3.9.5 mint Lesion Software Versions: 3.10.0 and 3.10.1	Mint Medical GmbH	Some software versions have a malfunction where they may show incorrect orientation labels for a specific subset of DICOM images.

Recall Class	Product Identification	Distribution	Affected Dates
II	Software Versions: 3.9.0 through 3.9.5 UDI-DI: 04260495880396 Software Versions: 3.10.0 and 3.10.1 UDI-DI: 04260495883106	2 units in California 1 unit in California	November and prior

For additional information, please visit: FDA Website (3.9.0) and FDA Website (3.10.0).