State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Reflexion recalls RXM1000 for Dosage Discrepancy Error

Recall Date	Product Description	Recalling Firm	Recall Reason
11/24/2021	**RefleXion Medical Radiotherapy System** System Label: "*** refleXion REF RXM1000 ***" Physics Guide/Treatment Delivery User Manual/Treatment Planning User Manual: "RefleXion X1 Model: RXM1000"	**Reflexion Medical, Inc.** Hayward, California	Due to dose discrepancy when delivering a plan to a patient in a Non-HFS (Head First Supine) orientation specifically in Feet First Supine (FFS).

Recall Class	Product Identification	Distribution	Affected Dates
II	Model: RXM1000 Serial Numbers/UDI Codes: X11001 / (01)00860003983805(11)210125 (21)X11001 X11002 / (01)00860003983805(11)210324 (21)X11002 X11003 / (01)00860003983805(11)210524 (21)X11003	2 Units in California	November 2021 and prior.

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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