## CALIFORNIA DEVICE RECALL INFORMATION SHEET

### Reflexion recalls RXM1000 for Dosage Discrepancy Error

<table>
<thead>
<tr>
<th>Recall Date</th>
<th>Product Description</th>
<th>Recalling Firm</th>
<th>Recall Reason</th>
</tr>
</thead>
</table>
| 11/24/2021  | **RefleXion Medical Radiotherapy System**  
System Label: "**refleXion REF 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). |

<table>
<thead>
<tr>
<th>Recall Class</th>
<th>Product Identification</th>
<th>Distribution</th>
<th>Affected Dates</th>
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</table>
| 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. |

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