



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

CooperVision recalls Biofinity XR Contact Lenses for Misalignment During Manufacture

Recall Date	Product Description	Recalling Firm	Recall Reason
3/8/2023	Biofinity XR Toric 6-pack Soft (hydrophilic) Contact Lens (extended wear)	CooperVision, Inc. West Henrietta, New York	Manufactured with misaligned axis resulting in lenses with the incorrect power, users may experience poor visual acuity
3/8/2023	Biofinity XR Toric Single Diagnostic lens Soft (hydrophilic) Contact Lens (extended wear)	CooperVision, Inc. West Henrietta, New York	Misaligned Axis

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI: N/A Lot Numbers: R24377024, R24377026, R24381716, R24416900	1 pack (6 lenses) California	January 2023
II	UDI: N/A Lot Numbers: R24377024, R24377026, R24381716, R24416900	1 pack (1 lens) California	January 2023

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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