State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Paragon Vision Sciences Recalls I See And Fargo Ortho-K Lens For No Coverage From FDA Approval

Recall Date	Product Description	Recalling Firm	Recall Reason
9/13/2023	**Isee Ortho-K Lens**	**PARAGON VISION SCIENCES, INC** Gilbert, Arizona	Manufactured lenses are not covered by existing FDA approval
9/13/2023	**Fargo Ortho-K Lens**	**PARAGON VISION SCIENCES, INC** Gilbert, Arizona	Manufactured lenses are not covered by existing FDA approval

Recall Class	Product Identification	Distribution	Affected Dates
II	**Isee Ortho-K Lens** All Lots , DI-B22208	83542 Units Nationwide including California	26 June, 2023, and prior
II	**Fargo Ortho-K Lens** All Lots, DI - B22208	18820 Units Nationwide including California	26 June, 2023, and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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