State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Scleral Patch Grafts by CorneaGen: Recall - Due to donor tested reactive for HIV-1/HIV-2 Plus O antibody and HIV NAT

Recall Date	Product Description	Recalling Firm	Recall Reason
1/11/2022	**CorneaGen Scleral Patches**	**CorneaGen** Seattle, Washington	CorneaGen is recalling the entire lot of Scleral Patch Grafts because Scleral Patch Grafts were obtained from a donor who tested reactive for HIV-1/HIV-2 Plus O antibody and HIV NAT, and were shipped prior to being medically cleared.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Scleral Patch Grafts** lot number W419221008338 Product Numbers: W419221008338005 to W419221008338019	10 Tissues distributed and transplanted in California	January 2022 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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