State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

ORIGEN BIOMEDICAL INC Recalls Accessory Sets Syringes due to the Sets Containing a Syringe that is not Qualified for the Accessory's Purpose.

Recall Date	Product Description	Recalling Firm	Recall Reason
2/21/2024	**Accessory Sets Syringes** 6ml syringe with a female luer with 15cm sealed SCD tubing, REF: RF-T15, and 60ml syringe on a female luer with 15cm sealed SCD tubing, REF: 15-RF60-T	**ORIGEN BIOMEDICAL, INC.** Austin, Texas	This device is being recalled due to the sets containing a syringe not qualified for the accessory's intended purpose. This was due to design changes to the syringe barrels and a polypropylene resin change that resulted in loss of gamma compatibility, for accessory set syringes that were gamma sterilized, which resulted in yellowed syringes.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Accessory Sets Syringes** REF/UDI-DI/Lots: RF-T15/10816203020205/ V23277, V23278, V23639; 15-RF60-T/10816203020571/V23281	23 Cartons in California California *Note: each carton contains 25 individual units of the device	February, 2024 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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