California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

DSAART LLC – AART Malar Implant Recall

Recall Date	Product Description	Recalling Firm	Recall Reason
12/18/2025	AART Malar Implant, silicone implants intended for facial (cheek) augmentation, available in left and right configurations (models 401-202-5 and 401-202-6).	DSAART LLC Carson City, NV, USA	Products deviated from established specifications and were distributed without required FDA premarket approval or clearance.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Model No.:** 401-202-5, 401-202-6 **UDI-DI:** **401-202-5:** B4904012025 **401-202-6:** B4904012026 **Lot Codes:** **401-202-5:** 24-01-014 **401-202-6:** 24-01-015 **S/N Range:** N/A	2 Units; Nationwide including California	September 2025 and prior.

For additional information, please visit the FDA Website.