California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Copan Wasp PhenoMATRIX

Recall Date	Product Description	Recalling Firm	Recall Reason
05/21/2025	PhenoMATRIX	Copan Wasp	AI-powered bacterial culture plate interpretation and workup software does not have Premarket Approval or pre-market notification (510(k)/de novo), so there is potential risk that the colony count and/or morphology information from images may not accurately reflect actual plate and may lead to inaccurate counts and/or morphology characteristics impacting patient diagnosis and subsequent care.

Recall Class	Product Identification	Distribution	Affected Dates
II	All software versions	2 units in California	May and prior

For additional information, please visit the FDA Website.