



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Dewei Medical Equipment Recalls DNA/RNA Preservation Kit for Lack of FDA Clearance

Recall Date	Product Description	Recalling Firm	Recall Reason
12/14/2022	Dewei DNA/RNA Preservation Kit Catalog number DW-80005-1B	Dewei Medical Equipment Co, Ltd Foshan, China	Products were distributed in the United States without FDA authorization or clearance.

Recall Class	Product Identification	Distribution	Affected Dates
I	LOT / EXP DW200628 27-Jun-21 DW200520 19-May-21 DW200520 19-May-21 DW201202 01-Dec-21 DW201202 1-Dec-21 DW210103 2-Dec-22 DW210926 25-Sep-22	1,348,000 units in California, Florida, Kentucky and Michigan	June 2021 – December 2022

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