State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Universal Meditech Recalls One Step Pregnancy And Ovulation Test For Distributing Without Marketing Distribution

Recall Date	Product Description	Recalling Firm	Recall Reason
11/1/2023	**One Step Pregnancy Test** REF 100-01	**UNIVERSAL MEDITECH INC.** Reedley, California	Universal Meditech Inc. was violatively distributing PrestiBio" Breastmilk Alcohol Test Strip, DiagnosUSÂ¿ SARS-CoV-2 Antibody (IgG/IgM) Test, HealthyWiser KetoFast" Ketone Test Strips and PrestiBio" Ketone Test Strips without marketing authorization. UMI is also recall their tests because they are going out of business and would not be able to continue fulfilling any post-market responsibilities of these distributed products. UMI claims to hold 510(k)s for the other devices, purchased the intellectual property in 2015 from the previous 510(k) holder, but FDA has been unable to verify this information. The devices may have unknown performance

			characteristics because the firm is unable to provide any documentation that the devices were manufactured in conformance with the Quality System regulation, including documentation (e.g., DHF) that the distributed devices had not been modified since original clearance in a way that could impact their safety and effectiveness, documentation of controlled storage temperature/humidity, and post-market surveillance documentation, such as complaints and adverse events.
11/1/2023	**One Step Ovulation Test** REF 200-01	**UNIVERSAL MEDITECH INC.** Reedley, California	Universal Meditech Inc. was violatively distributing PrestiBio" Breastmilk Alcohol Test Strip, DiagnosUSÂ¿ SARS-CoV-2 Antibody (IgG/IgM) Test, HealthyWiser KetoFast" Ketone Test Strips and PrestiBio" Ketone Test Strips without marketing authorization. UMI is also recall their tests because they are going out of business and would not be able to continue fulfilling any post-market responsibilities of these distributed products. UMI claims to hold 510(k)s for

			the other devices, purchased the intellectual property in 2015 from the previous 510(k) holder, but FDA has been unable to verify this information. The devices may have unknown performance characteristics because the firm is unable to provide any documentation that the devices were manufactured in conformance with the Quality System regulation, including documentation (e.g., DHF) that the distributed devices had not been modified since original clearance in a way that could impact their safety and effectiveness, documentation of controlled storage temperature/humidity, and post-market surveillance documentation, such as complaints and adverse events.

Recall Class	Product Identification	Distribution	Affected Dates
II	**One Step Pregnancy Test** Model Number: 100-01 UDI-DI Code: B512100011 Lot Numbers: 3-H25052-20UMI 3-H07102-20UMI	147000 Units Nationwide including California	22 May 2023 and prior
II	**One Step Ovulation Test** Model Number: 200-01 UDI-DI Code: B512200011 Lot Numbers: 3-L12121-20UMI 3-L07102-20UMI	100000 Units Nationwide including California	22 May 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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