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 Healthywiser Ketofast" Ketone Test Strips For Distributing Without Market Authorization**

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|---|---|---|---|
| 11/1/2023 | **Healthywiser Ketofast" Ketone Test Strips**<br>REF 900-1K 150 test strips | **UNIVERSAL MEDITECH INC.**<br>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 |

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| | | | 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 | **HealthyWiser KetoFast" Ketone Test Strips**<br>Model Number: 900-1K UDI-DI Code: Lot Numbers: URS-1-2104-02 | 1500 Units Nationwide including California | 22 May 2023 and prior |

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE