



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Universal Meditech Inc. Recalls Diagnosus One Step Ovulation And Menopausal Test Strips For Inability To Continue Fulfilling Any Post-Market Responsibilities

Recall Date	Product Description	Recalling Firm	Recall Reason
11/1/2023	Diagnosus One Step LH Ovulation Test Strip REF 200-07	UNIVERSAL MEDITECH INC. Reedley, California	<p>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</p>

			<p>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.</p>
<p>11/1/2023</p>	<p>Diagnosus® One Step FSH Menopausal Test (Strip) REF 210-07</p>	<p>UNIVERSAL MEDITECH INC. Reedley, California</p>	<p>Universal Meditech Inc. was violatively distributing PrestiBio" Breastmilk Alcohol Test Strip, DiagnosUS® 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</p>

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Recall Class	Product Identification	Distribution	Affected Dates
II	<p>Diagnosis One Step LH Ovulation Test Strip Model Number: 200-07 UDI-DI Code: None Lot Numbers: All products manufactured after March 2021 to include: LH-S-2204-01-S LH-S-2111-01-S</p>	<p>525 Units Nationwide including California</p>	<p>22 May 2023 and prior</p>

II	Diagnosusâ¿ One Step FSH Menopausal Test (Strip) Model Number: 210-07 UDI-DI Code: None Lot Numbers: All products manufactured after March 2021 to include: FSH-S-2106-01 FSH-S-2108-01 FSH -S-2111-01-S	2400 Units Nationwide including California	22 May 2023 and prior
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