Universal Meditech Recalls Healthywiser Uritest For Distributing Without Marketing Authorization

<table>
<thead>
<tr>
<th>Recall Date</th>
<th>Product Description</th>
<th>Recalling Firm</th>
<th>Recall Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/1/2023</td>
<td>Healthywiser Uritest” 10 Parameter Reagent Test Strips For Urinalysis REF 900-10</td>
<td>UNIVERSAL MEDITECH INC. Reedley, California</td>
<td>Universal Meditech Inc. was violatively distributing PrestiBio&quot; Breastmilk Alcohol Test Strip, DiagnosUSÃ¢â€šÂ¬ SARS-CoV-2 Antibody (IgG/IgM) Test, HealthyWiser KetoFast&quot; Ketone Test Strips and PrestiBio&quot; 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</td>
</tr>
</tbody>
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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.

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<th>Date</th>
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<td>11/1/2023</td>
<td>Healthywiser Uritest&quot; UTI Test Strips</td>
<td>UNIVERSAL MEDITECH INC. Reedley, California</td>
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<td></td>
<td>REF 900-UTI</td>
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<tr>
<th>Recall Class</th>
<th>Product Identification</th>
<th>Distribution</th>
<th>Affected Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>II</td>
<td>Healthywiser Uritest&quot; 10 Parameter Reagent Test Strips For Urinalysis</td>
<td>122500 Units Nationwide including California</td>
<td>22 May 2023 and prior</td>
</tr>
<tr>
<td></td>
<td>Model Number: 900-10</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>UDI-DI Code: None</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Lot Numbers: URS-1-2104-01</td>
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<td></td>
<td>URS-1-2102-02 URS-1-2105-01</td>
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<tr>
<td></td>
<td>URS-1-2106-02 URS-1-2110-02</td>
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</tr>
</tbody>
</table>
| II | HealthyWiser UriTest™ UTI Test Strips  
Model Number: 900-UTI  
UDI-DI Code: None  
Lot Numbers: URS-1-2102-03 URS-1-2106-01 URS-1-2202-01-Q URS-1-2204-01 URS-1-2207-01 URS-1-2209-01 | 5960 Units  
Nationwide including California | 22 May 2023 and prior |

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