**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

Impedimed Limited Recalls Sozo Bilateral Arm L-Dex Software For Lacking The Level Of Sensitivity To Help Detect Early Signs Of Lymphedema

<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>Sozo Bilateral Arm L-Dex Software</td>
<td>IMPEDIMED LIMITED Pinkenba, Australia</td>
<td>Bilateral L-Dex assessment software does not have the same level of sensitivity to help detect early signs of lymphedema as the unilateral arm L-Dex assessment, which could result in under-recognition of early lymphedema, which could result in delay in early intervention, and more aggressive intervention.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recall Class</th>
<th>Product Identification</th>
<th>Distribution</th>
<th>Affected Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>II</td>
<td>Sozo Bilateral Arm L-Dex Software</td>
<td>354 Units Nationwide including California</td>
<td>17 August 2023 and prior</td>
</tr>
</tbody>
</table>

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)