State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

# 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**

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|---|---|---|---|
| 11/1/2023 | **Sozo Bilateral Arm L-Dex Software** | **IMPEDIMED LIMITED** Pinkenba, Austrailia | 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. |

| Recall Class | Product Identification | Distribution | Affected Dates |
|---|---|---|---|
| II | **Sozo Bilateral Arm L-Dex Software** UDI-DI: B277SFT0250. Software v4.1 and v5.0 | 354 Units Nationwide including California | 17 August 2023 and prior |

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov