California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Nuwellis Inc nuwellis AquaFlexFlow UF 500 Plus

Recall Date	Product Description	Recalling Firm	Recall Reason
01/16/2025	nuwellis AquaFlexFlow UF 500 Plus, REF 114156, Catalog Number A06163, extracorporeal blood circuit which is used with the Aquadex SmartFlow or Aquadex FlexFlow System	Nuwellis Inc	The AquaFlexFlow UF 500 Plus extracorporeal blood circuit used with the Aquadex SmartFlow and FlexFlow Systems may indicate "Ultrafiltrate Weight Mismatch" or Excessive Weight Mismatch Alarms while in use. If not addressed, this failure could result in excess fluid removal from a patient leading to Acute Volume Depletion. This failure is especially serious when the Aquadex System is being used on pediatric patients.

Recall Class	Product Identification	Distribution	Affected Dates
I	Lot Numbers: 22697 - 22740	845 units nationwide	December and prior

For additional information, please visit the FDA Website.