California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Waldemar Link GmbH & Co. KG (Mfg Site) Modular Stem Cylindrical, Tilastan

Recall Date	Product Description	Recalling Firm	Recall Reason
03/17/2025	Modular Stem cylindrical, Tilastan press-fit cementless L= 80 mm DIA = 11 mm Product Code: 880-601/11 Modular Stem cylindrical, Tilastan press-fit cementless L= 80 mm DIA = 12 mm Product Code: 880-601/12 Modular Stem cylindrical, Tilastan press-fit cementless L= 80 mm DIA = 13 mm Product Code: 880-601/13	Waldemar Link GmbH & Co. KG (Mfg Site)	A problem was discovered during the scanning process of the outer carton label because of an incorrect GTIN on the label, which is a GTIN for a different product.

Recall Class	Product Identification	Distribution	Affected Dates
II	Product Code: 880-601/11 UDI-DI: 04026575443925 Lot Numbers: 1943294 - 2049174	2 units in California	February and prior

	Product Code: 880-601/12 UDI-DI: 04026575443932 Lot Numbers: 1943274 - 2049175 Product Code: 880-601/13 UDI-DI: 04026575443949 Lot Numbers: 1943277, 1943280		

For additional information, please visit: FDA Website (11 mm), FDA Website (12 mm), and FDA Website (13 mm).