State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Link Bio Recalls Tibial Orthopedic Prosthesis due to Blind Screws that cannot be Loosened Intraoperatively

Recall Date	Product Description	Recalling Firm	Recall Reason
5/24/2022	**Endo Model Modular Rotational Tibia** Small (Model No #15-2814/02), Medium (Model No #15-2814/03), and Large (Model No #15-2814/04). orthopedic prosthesis.	**Waldemar Link GmbH & Co. KG** Norderstedt, Germany	There is a risk that blind screws of the modular tibial component cannot be loosened intraoperatively. This may lead to prolongation of surgery due to an intraoperative change in procedure.
5/24/2022	**Endo Model Modular Femur and Tibia** PorEx. orthopedic prosthesis. Model Nos.: Small, Right 15-3816/11, Small, Left 15-3816/12, Medium, Right 15-3817/11	**Waldemar Link GmbH & Co. KG** Norderstedt, Germany	Blind screws of the modular tibial component cannot be loosened intraoperatively
5/24/2022	**Tibial Component** orthopedic prosthesis. Model Nos: Small, W 16-2817/02 Large, W 16-2817/07	**Waldemar Link GmbH & Co. KG** Norderstedt, Germany	Blind screws of the modular tibial component cannot be loosened intraoperatively

Recall Class	Product Identification	Distribution	Affected Dates
II	**Endo Model Modular Rotational Tibia** UDI-DI 04026575316281 (Small) 04026575316298 (Medium) 04026575316304 (Large) Serial/Lot Numbers: 211115/2111 210602/2717 210420/0762	3 Devices in California	May 2022 and prior

II	**Endo Model Modular Femur and Tibia** UDI-DI 04026575034741 Small, Right; 04026575034758 Small, Left; 04026575164042 Medium, Right Serial/Lot Numbers: 200818/1732 200623/4154 200812/1511 210302/2440	4 Devices in California	May 2022 and prior
II	**Tibial Component** UDI-DI: 04026575359202 Small, W; 04026575359219 Large, W; Serial/Lot Numbers: 210314/1872 201002/1687	2 Devices in California	May 2022 and prior

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