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Class 2 Device Recall EndoModel, Replacement Set, Tibial Plateau, right/left, L, UHMWPE, CoCrMo, Rotating Hinge

Class 2 Device Recall EndoModel, Replacement Set, Tibial Plateau, right/left, L, UHMWPE, CoCrMo, Rotating Hinge

See Related Information[22]

Date Initiated by Firm	July 06, 2026
Date Posted	August 11, 2026
Recall Status[1]	Open[3], Classified
Recall Number	Z-2934-2026
Recall Event ID	99405[23]
510(K)Number	K143179[24]
Product Classification	Prosthesis, knee, femorotibial, constrained, cemented, metal/polymer[25] - **Product Code** KRO[26]
Product	Endo-Model, Replacement Set, Tibial Plateau, right/left, L, UHMWPE, CoCrMo, Rotating Hinge Item Number 15-0027/16
Code Information	UDI-DI 04026575432134 Lot for Implant REF 15-0027/16: 2604069
FEI Number	3003386935
Recalling Firm/ Manufacturer	Waldemar Link GmbH & Co. KG (Mfg Site) Ost Str. 4-10 Norderstedt Germany
For Additional Information Contact	Terry Sheridan Powell 494053995150
Manufacturer Reason for Recall	The affected Endo-Model replacement set for a Rotating Hinge tibial plateau incorrectly contains a Pure Hinge plateau. The incorrect plateau could lead to a prolonged or modified surgery as the plateau cannot be inserted and an alternative product would be needed. If the incorrect plateau were to be implanted, this is associated with increased risk of wear, which could result in a reduced standing time of the implant.
FDA Determined Cause [2]	Process change control
Action	Foreign manufacturer, Waldemar Link GmbH & Co KG, notified importer LinkBio Corp. on 7/6/2026 via email. LinkBio then notified the single US consignee by email/Docusign on 7/7/2026. Customer was instructed to return the affected product to LinkBio.
Quantity in Commerce	1 US; 9 OUS
Distribution	Domestic US distribution to Indiana. OUS distribution to Belarus and Germany.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the

recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database 510(K)s with Product Code = KRO[29]

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