



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Osteomed 1.6mm x 4mm Profile Zero Auto-Drive Screw for Undersized Screwhead

Recall Date	Product Description	Recalling Firm	Recall Reason
7/19/2023	1.6mm x 4mm Profile Zero Auto-Drive Screw REF: 218-1604	Osteomed, LLC Addison, Texas	Screws for osteotomies have contain an undersized screwhead which has the potential to pass through the plate hole.

Recall Class	Product Identification	Distribution	Affected Dates
II	1.6mm x 4mm Profile Zero Auto-Drive Screw Lot # 1177027, 1177718, 1177812 / UDI-DI: (01)00845694034258	400 Units in California	May 2023 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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