



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Xtant Medical recalls X060-0270 Axle Interspinous Fusion System for Out of Specification Proximal Opening that Prevents Crossbar Plate Engagement

Recall Date	Product Description	Recalling Firm	Recall Reason
12/29/2021	X060-0270 8mm Titanium Insert Axle Interspinous Fusion System	Xtant Medical Belgrade, Montana	Presence of undeclared methanol

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI (Primary DI Number): M697X06002701/\$\$7058963W Lot Number: 058963	3 Units in California	December 2021 and prior

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

