California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

XTANT Medical Holdings, Inc Irix-A Integrated Lumbar Fusion System

Recall Date	Product Description	Recalling Firm	Recall Reason
02/19/2025	Irix-A Integrated Lumbar Fusion System, Model Number X080-423011-08PC (Spacer Assy, 42 X 30 X 8¿, 11mm, PC (STERILE)) and Model Number X080-382819-08PC (Spacer ASSY, 38 X 28 X 8¿, 19mm, PC, (STERILE))	XTANT Medical Holdings, Inc	Certain implants in the Irix-A Lumbar Fusion System were distributed while labeled with an incorrect expiration date.

Recall Class	Product Identification	Distribution	Affected Dates
II	Model: X080-382819-08PC-STR UDI-DI: M697X08038281908PCSTR1 Lot Number: 054961 Model Number: X080-423011-08PC-STR UDI-DI: M697X08042301108PCSTR1 Lot Number: 053028	3 units in California	January and prior

For additional information, please visit the FDA Website.