California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

SIN Sistema de Implante Nacional S.A Implant Epikut S Plus CM 16-Degrees

Recall Date	Product Description	Recalling Firm	Recall Reason
01/15/2025	Implant Epikut S Plus CM 16-Degrees 4,5 X 18,0 mm REF: ILM 4518N	SIN Sistema de Implante Nacional S.A.	Dental implant box incorrectly labels the diameter as 4,5 X 18,0 mm, but the internal label correctly labels the diameter as 4,0 X 18,0 mm; if the dentist drills the bone with the larger diameter stated on the box, the smaller diameter implant, will become loose and will not fit, which may necessitate an additional surgery.

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI-DI: 07899995273437 Lot: X010469757 Expiration: 2028/01	7 units in California	September and prior

For additional information, please visit the FDA Website.