



California Device Recall Information Sheet

Food and Drug Branch - Device Recalls

Aerin Medical, Inc. VivAer Stylus

Recall Date	Product Description	Recalling Firm	Recall Reason
01/06/2025	Aerin Medical VivAer Stylus, sterile REF CAT1785 (individual stylus) REF CAT500 (5-pack)	Aerin Medical, Inc.	Some units in a single production lot were programmed incorrectly which will result in the VivAer Stylus being incorrectly recognized as RhinAer Stylus when connected to the Aerin Console.

Recall Class	Product Identification	Distribution	Affected Dates
II	Lot: #10235 Exp: 2026-05-01 UDI: (01)08886479300269(17)260501 (10)10235	20 units in California	November and prior

For additional information, please visit the FDA Website.