



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET
Zeltiq Aesthetics Recalls Vacuum Applicator for Paradoxical Hyperplasia

Recall Date	Product Description	Recalling Firm	Recall Reason
6/09/2022	Vacuum Applicator CoolMax BRZ-AP1-080-000 UDI-DI: 00816417020230 CoolCore BRZ-AP1-063-000 UDI-DI: 00816417020179 CoolCurve BRZ-AP1-062-000 UDI-DI: 00816417021008 CoolCurve+ BRZ-AP1-064-000 UDI-DI: 00816417020193 CoolFit BRZ-AP1-066-000 UDI-DI: 00816417020216	Zeltiq Aesthetics INC. Pleasanton, California	An increase complaint rate for adverse event Paradoxical Hyperplasia (HP) during the 2019 to 2021 timeframe

Recall Class	Product Identification	Distribution	Affected Dates
II	Serial No: V0212015294011 - V0802010228001	2030 Units from 409 Customers in California	January 2019 to December 2023

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

