



Food and Drug Branch – Device Recalls

**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Cytrellis Biosystems Recall Cytrellis Ellacor System for Irregular Core Patterns**

Recall Date	Product Description	Recalling Firm	Recall Reason
6/08/2023	<b>Cytrellis Ellacor System</b> Micro-Coring Technology-Dermal Micro-Coring System intended for the treatment of moderate and severe wrinkles in the mid and lower face. Model #: Gen 4	<b>CYTRELLIS BIOSYSTEMS, INC.</b> Woburn, Massachusetts	Irregular core patterns could cause potential overlap of cores at the 8% setting, potentially leading to prolonged healing, irregularities in patient skin texture post-treatment, and/or scarring.

Recall Class	Product Identification	Distribution	Affected Dates
II	<b>Cytrellis Ellacor System</b> UDI-DI: B933ELCON010 All serial numbers	25 Units in California	April 2023 and Prior

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

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