California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Lumithera Inc Recalls Valeda Light Delivery System

Recall Date	Product Description	Recalling Firm	Recall Reason
07/09/2025	Brand Name: Valeda Light Delivery System Product Name: Light Based Device for Dry Age Related Macular Degeneration Product Description: Light Based Device for Dry Age Related Macular Degeneration Component: No	Lumithera Inc	U.S. customers were shipped devices that were configured for the European Union and were unable to plug the device in the electrical outlet.

Recall Class	Product Identification	Distribution	Affected Dates
III	Lot Code: UDI-DI +B749200001030/$$+720172/16D20250311T; Serial Number 20172 UDI-DI +B749200001030/$$+720166/16D20250311W; Serial Number 20166 UDI-DI +B749200001030/$$+720167/16D20250311X; Serial Number 20167 UDI-DI +B749200001030/$$+720168/16D20250311Y; Serial Number 20168 UDI-DI +B749200001030/$$+720169/16D20250311Z; Serial Number 20169 UDI-DI +B749200001030/$$+720175/16D20250311W; Serial Number 20175 UDI-DI +B749200001030/$$+720177/16D20250311Y; Serial Number 20177 UDI-DI +B749200001030/$$+720178/16D20250311Z; Serial Number 20178 Update 14 May 2025: UDI-DI +B749200001030/$$+720170/16D20250311R; Serial Number 20170	US Nationwide distribution in the states of AZ, CA, FL, IL, ND, TN, TX. **2 units** were shipped to the state of California. One to Retina Specialists of Beverly Hills(Beverly Hills, CA), and one to Eye-Q Vision Care (Fresno, CA)	May 2025 and prior.

For additional information, please visit the FDA Website.