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Class 2 Device Recall Pearle Vision 1 day



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Class 2 Device Recall Pearle Vision 1 day



Date Initiated by Firm	August 12, 2026
Date Posted	September 18, 2026
Recall Status ¹	Open ³ , Classified
Recall Number	Z-3248-2026
Recall Event ID	99766 ²³
510(K)Number	K130331 ²⁴
Product Classification	Lens, contact, (disposable) ²⁵ - Product Code MVN ²⁶
Product	Brand Name: Pearle Vision 1 day Product Name: (somofilcon A) Contact Lens Model/Catalog Number: Pearle Vision 1 day
Code Information	Pearle Vision 1 day; Carton Lot # 11727620152030; Blister Lot # CB132348;
FEI Number	3005724763
Recalling Firm/ Manufacturer	CooperVision, Inc. 180 Thruway Park Dr West Henrietta NY 14586-9798
For Additional Information Contact	Annette Nelson 585-756-9300
Manufacturer Reason for Recall	A small number of lenses within the affected lot are of the incorrect power.
FDA Determined Cause ²	Process control
Action	On August 24, 2026 URGENT MEDICAL DEVICE CORRECTION letters were sent to customers. Actions to be taken: 1. Please stop any further distribution of products from the designated lot number. 2. Dispose of the affected product in your inventory or that is returned to you. 3. Within the next five (5) business days, please complete the response form provided and return it. If you have no lenses from these specified lots, please put 0 in Quantity and return the form. 4. We recommend authorized distributors contact your accounts, and Eye Care Practitioners contact your patients who have received the affected product, with the enclosed Customer Communication Letter . 5. Please instruct any patients to return any affected product to their Eye Care Practitioner or purchase location for replacement or credit.
Quantity in Commerce	3060

Distribution

US Nationwide distribution in the states of MN, OH, WI.

Total Product Life Cycle [TPLC Device Report](#)²⁷

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)²⁸.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database[510\(K\)s with Product Code = MVN](#)²⁹**Links on this page:**

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