Class 2 Device Recall Softmed Breathables Advanced Toric

See Related Information[22]

Date Initiated by Firm	September 22, 2026
Date Posted	October 22, 2026
Recall Status[1]	Open[3], Classified
Recall Number	Z-0204-2027
Recall Event ID	99936[23]
510(K)Number	K160803[24] K213164[25] K220070[26]
Product Classification	Lenses, soft contact, daily wear[27] - **Product Code** LPL[28]
Product	Generic Name: Softmed Breathables Advanced Toric (fanfilcon A) Soft (Hydrophilic) Contact Lens; Model/Catalog Number: Softmed Breathables Advanced Toric Product Description: 55% water content, toric, silicone hydrogel contact lens for daily wear, frequent replacement. Blister packaged.
Code Information	Model/Catalog Number: Softmed Breathables Advanced Toric; UDI-DI: N/A Lot numbers: 19486120027517, 19486120030515, 19486120035532, 19486120051506, 19486170015507, 19486170016513, 19486170016521, 19486170017507, 19486170017509, 19486170017512, 19486170019512, 19486170019514, 19486170021021, 19486170021518, 19486170022503, 19486170022504, 19486170023528, 19486170025508, 19486170026021, 19486170027034, 19486170027504, 19486170027524, 19486170028518, 19486170030023, 19486170030034, 19486170031023, 19486170031034, 19486170032030, 19486170032036, 19486170032504, 19486170033501, 19486170034001, 19486170034032, 19486170034038, 19486170039040, 19486170040030, 19486170041032, 19486170042018, 19486170042032, 19486170043003, 19486170043028, 19486170043030, 19486170043032, 19486170043502, 19486170044017, 19486170045011, 19486170047002, 19486170047007, 19486170047011, 19486170048011, 19486170049004, 19486170049006, 19486170049009, 19486170049011, 19486170050003, 19486170050004, 19486170050007, 19486170050019, 19486170051002, 19486170051006, 19486170051024, 19486170052002, 19486170052005, 19486170052009, 19486170052015, 19486170053015, 19486170053024, 19486170054015, 19486170054016, 19486170055000, 19486170055018, 19486170055026, 19486170056000, 19486170056014, 19486170057005, 19486170059018, 19486170060008, 19486170060012, 19486170060014, 19486170061008, 19486170061014, 19486170061018, 19486170064014, 19486170065008, 19486170068010, 19486170069010, 19487120020526, 19487120026512, 19487120027506, 19487120043038, 19487120046502, 19487120048036, 19487120051003, 19487120061007, 19487120067007, 19487120071014, 19487120075016, 19487120077016, 19487120079014, 19487120080014, 19487170006516, 19487170012505, 19487170015501, 19487170016524, 19487170017030, 19487170019503, 19487170022001, 19487170022021, 19487170023021, 19487170025011, 19487170026019, 19487170028011, 19487170028013, 19487170029019, 19487170030017, 19487170030019, 19487170031026, 19487170031028, 19487170031032, 19487170032011, 19487170032017, 19487170032024, 19487170033005, 19487170033009, 19487170034002, 19487170034015, 19487170035002, 19487170035022, 19487170036020, 19487170037000, 19487170037011, 19487170038005, 19487170038018, 19487170039018, 19487170040000, 19487170042000, 19487170044000, 19487170047006, 19487170048012, 19487170053008, 19488120012522, 19488120015512, 19488120017519, 19488120023021, 19488120030013, 19488120032017, 19488120033028, 19488120034005, 19488120035018, 19488120037018, 19488120042020, 19488120044000, 19488170005507, 19488170006504, 19488170007501,

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FEI Number 3005724763

Recalling Firm/ Manufacturer

CooperVision, Inc.

180 Thruway Park Dr

West Henrietta
NY

14586-9798

For Additional Information Contact	Annette Nelson 1-925-6604471
Manufacturer Reason for Recall	The affected products bear an incorrect statement on the carton packaging indicating that the product is "Indicated for Extended Wear". However, this product is intended for daily wear, and the extended-wear statement should not have appeared on the affected carton labeling. This product is not approved by the U.S. Food and Drug Administration (FDA) for extended wear use.
FDA Determined Cause [2]	Labeling design
Action	On September 22, 2026, URGENT MEDICAL DEVICE RECALL letters were sent to customers. Actions to be taken: 1. Examine product in your possession for any affected product. 2. If the product packaging bears the Indicated for Extended Wear statement or the lot number on the carton appears in the list of affected lot numbers, please stop any further use or distribution of products from the designated lot number(s). 3. Please return the product to your authorized distributor or your Eye Care Practitioner. 4. We recommend Eye Care Practitioners contact your patients who have received the affected product. 5. Please instruct patients to return any affected product to their purchase location. 6. For questions or assistance regarding product return, credit or replacement if necessary, please contact your authorized distributor, Eye Care Practitioner, or purchase location.
Quantity in Commerce	230856
Distribution	US Nationwide distribution in the states of FL, KY, MI.
Total Product Life Cycle	TPLC Device Report[29]

[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[30].

[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 = LPL[31]

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