Class 2 Device Recall AKREOS AO Micro Incision Lens

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See Related Information[21]

Date Posted	February 20, 2014
Recall Status[1]	Open
Recall Number	Z-1062-2014
Recall Event ID	67283[22]
Premarket Approval PMA Number	P060022[23]
Product Classification	Intraocular Lens[24] - **Product Code** HQL[25]
Product	Bausch & Lomb AKREOS AO Micro Incision Lens The Akreos IOL intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia secondary to the removal of a cataractous lens in adult patients.
Code Information	Model Numbers(s): AO60 and MI60L
Recalling Firm/ Manufacturer	Bausch & Lomb Surgical, Inc. 21 N Park Place Blvd Clearwater, Florida 33759-3917
For Additional Information Contact	Glenn Mattei 727-724-6600
Manufacturer Reason for Recall	Lens was manufactured with incorrect raw material.
FDA Determined Cause [2]	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Nonconforming Material/Component
Action	The firm, Bausch + Lomb, telephoned and sent an "URGENT - MEDICAL DEVICE RECALL" letter dated October 17, 2013 to its customers. The letter described the product, problem and actions to be taken. The customers were instructed to: 1) Determine the disposition of the lenses; 2) Complete and provide the enclosed acknowledgement form to the sales respresentatives collecting the lenses, and 3) Return all unused products. If you have any questions, please contact Bausch + Lomb at (800) 338-2020.
Quantity in Commerce	336 IOLs (283 IOLs in the US, 53 IOLs outside the US)
Distribution	Worldwide Distribution: US (nationwide) and Internationally to: Great Britain, France, Spain, Portugal, Sweden, Russia and Guadeloupe.
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

PMA Database	PMAs with Product Code = HQL and Applicant = BAUSCH & LOMB, INC.[28]

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