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Class 2 Device Recall AKREOS AO Micro Incision Lens

New Search

Date Posted: February 20, 2014
Recall Status: Open
Recall Number: Z-1062-2014
Recall Event ID: 67283
Premarket Approval PMA Number: P060022
Product Classification: Intraocular Lens - Product Code HQL
Product: Bausch & Lomb AKREOS AO Micro Incision Lens
The Arkres 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: 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 representatives 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

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