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**Class 2 Device Recall AKREOS AO Micro Incision Lens**

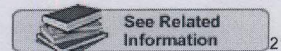


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**Class 2 Recall  
 AKREOS AO Micro Incision Lens**



<b>Date Posted</b>	February 20, 2014
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1062-2014
<b>Recall Event ID</b>	<u>67283</u> <sup>22</sup>
<b>Premarket Approval PMA Number</b>	<u>P060022</u> <sup>23</sup>
<b>Product Classification</b>	<u>Intraocular Lens</u> <sup>24</sup> - <b>Product Code</b> <u>HQL</u> <sup>25</sup>
<b>Product</b>	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.
<b>Code Information</b>	Model Numbers(s): AO60 and MI60L
<b>Recalling Firm/Manufacturer</b>	Bausch & Lomb Surgical, Inc. 21 N Park Place Blvd Clearwater, Florida 33759-3917
<b>For Additional Information Contact</b>	Glenn Mattei 727-724-6600
<b>Manufacturer Reason for Recall</b>	Lens was manufactured with incorrect raw material.
<b>FDA Determined Cause<sup>2</sup></b>	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Nonconforming Material/Component
<b>Action</b>	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.
<b>Quantity in Commerce</b>	336 IOLs (283 IOLs in the US, 53 IOLs outside the US)
<b>Distribution</b>	Worldwide Distribution: US (nationwide) and Internationally to: Great Britain, France, Spain, Portugal, Sweden, Russia and Guadeloupe.
<b>Total Product Life Cycle</b>	<u>TPLC Device Report</u> <sup>26</sup>

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55](#)<sup>27</sup>  
<sup>2</sup> 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.](#)<sup>28</sup>

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