Date Initiated by Firm: November 05, 2018
Create Date: December 18, 2018
Recall Status: Open, Classified
Recall Number: Z-0628-2019
Recall Event ID: 81600
PMA Number: P910056
Product Classification: Intraocular lens - Product Code HQL
Product: enVista One Piece Hydrophobic Acrylic Intraocular lens -

Is indicated for primary implantation for the visual correction of aphakia in adult patients in whom the cataractous lens has been removed. The lens is intended for placement in the capsular bag.

Code Information: Model MX60E and specific lots of the following SKU's: MXUE0000, MXUE0100, MXUE0200, MXUE0300, MXUE0400, MXUE0500, MXUE0600, MXUE0700, MXUE0800, MXUE0900, MXUE1000, MXUE1050, MXUE1100, MXUE1150, MXUE1200, MXUE1250, MXUE1300, MXUE1350, MXUE1400, MXUE1450, MXUE1500, MXUE1550, MXUE1600, MXUE1650, MXUE1700, MXUE1750, MXUE1800, MXUE1850, MXUE1900, MXUE1950, MXUE2000, MXUE2050, MXUE2100, MXUE2150, MXUE2200, MXUE2250, MXUE2300, MXUE2350, MXUE2400, MXUE2450, MXUE2500, MXUE2550, MXUE2600, MXUE2650, MXUE2700, MXUE2750, MXUE2800, MXUE2850, MXUE2900, MXUE2950, MXUE3000, MXUE3100, MXUE3200, MXUE3300, and MXUE3400.

Recalling Firm/Manufacturer: Bausch & Lomb Surgical, Inc.
21 N Park Place Blvd
Clearwater FL 33759-3917

For Additional Information Contact: 727-724-6600
Manufacturer Reason for Recall: Cosmetic imperfections on the surface of some lenses.

FDA Determined Cause: Process control

Action: On Nov 5, 2018 Bausch & Lomb sent letters to all their consignees, requesting the following: 1. Review and quarantine your inventory of all the impacted lots for this recall. 2. Complete the enclosed Medical Device Voluntary Recall Acknowledgement Form and contact B&L to obtain a return material authorization number and arrange for a pick up of