FDA

Class 2 Device Recall enVista

See Related Information[22]

Date Initiated by Firm	November 05, 2018
Create Date	December 18, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0628-2019
Recall Event ID	81600[23]
PMA Number	P910056[24]
Product Classification	intraocular lens[25] - **Product Code** HQL[26]
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 [2]	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

14-1-2019