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## Class 2 Device Recall enVista

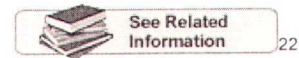


6 510(k) | DeNovo<sup>6</sup> | Registration & Listing<sup>9</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup> | PMA<sup>12</sup> | HDE<sup>13</sup> | Classification<sup>14</sup> | Standards<sup>15</sup>  
 CFR Title 21<sup>16</sup> | Radiation-Emitting Products<sup>17</sup> | X-Ray Assembler<sup>18</sup> | Medsun Reports<sup>19</sup> | CLIA<sup>20</sup> | TPLC<sup>21</sup>

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### Class 2 Device Recall enVista



<b>Date Initiated by Firm</b>	November 05, 2018
<b>Create Date</b>	December 18, 2018
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-0628-2019
<b>Recall Event ID</b>	81600 <sup>23</sup>
<b>PMA Number</b>	<u>P910056</u> <sup>24</sup>
<b>Product Classification</b>	<u>intraocular lens</u> <sup>25</sup> - <b>Product Code</b> <u>HQL</u> <sup>26</sup>
<b>Product</b>	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.
<b>Code Information</b>	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.
<b>Recalling Firm/ Manufacturer</b>	Bausch & Lomb Surgical, Inc. 21 N Park Place Blvd Clearwater FL 33759-3917
<b>For Additional Information Contact</b>	727-724-6600
<b>Manufacturer Reason for Recall</b>	Cosmetic imperfections on the surface of some lenses.
<b>FDA Determined Cause<sup>2</sup></b>	Process control
<b>Action</b>	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