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**Class 2 Device Recall Prescription eyeglass safety lenses**



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**Class 2 Recall  
Prescription eyeglass safety lenses**



<b>Date Posted</b>	December 16, 2014
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-0167-2015
<b>Recall Event ID</b>	<u>69345</u> <sup>23</sup>
<b>Product Classification</b>	Lens, Spectacle, Non-Custom (Prescription) <sup>24</sup> - <b>Product Code</b> HQG <sup>25</sup>
<b>Product</b>	Prescription eyeglass safety lenses. Vision correction
<b>Code Information</b>	No lot codes are applied. The recalled products contain the following model numbers LC Elite 1.50 80mm HC, LC Elite 1.50 80mm Suntech GRY, LC Elite Poly 75mm Suntech GRY, LC Elite Poly 77mm HC, LC SFSV 1.67 Suntech3 GRY, LC SFSV 75mm Trivex STG, LC Short Elite Poly 77mm HC, LC Short Elite Poly Suntech GRY, Poly FT-28 with scratch coat, Poly LifeRX Photo FT 7x28 Brown, Poly LifeRx Photo FT-28 Gray, Poly SFSV LifeRx Photo Gray, Poly SFSV with scratch coat, SF SUMMIT ECP 167 TRN7 GY 70mm, SF SUMMIT ECP 167 TRN7 GY 75mm, SF SV 1.53 T7 GY 75mm, SF SV 70mm PHOENIX COT, SFSV 167 Clear, Transitions VI Gray D28
<b>Recalling Firm/Manufacturer</b>	Eyemart Express Ltd 13800 Senlac Dr Ste 200 Farmers Branch, Texas 75234-8823
<b>Manufacturer Reason for Recall</b>	Prescription eyeglass safety lenses did not meet specifications.
<b>FDA Determined Cause<sup>2</sup></b>	TRAINING: Employee Error
<b>Action</b>	Eyemart Express sent an Important Recall Notice dated September 12, 2014, to all affected customers. The notice identified the product, the problem, and the action to be taken by the customer. Customers were instructed to call Eyemart Express Customer Service at 1-888-DRBARNES to discuss their lens replacement options of if they have any questions.
<b>Quantity in Commerce</b>	76 pairs of eyeglasses
<b>Distribution</b>	Nationwide Distribution including AK, AL, AR, CA, LA, MD, MO, MS, MT, NC, ND, NM, OH, OK, TN, SC, TX, VA, WI, and WV.
<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.

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