Class 2 Device Recall Cflex Intraocular Lens

Date Initiated by Firm: August 09, 2016
Create Date: September 28, 2018
Recall Status: Open, Classified
Recall Number: Z-3282-2018
Recall Event ID: 80943
PMA Number: P060011
Product Classification: Intraocular lens
Product: C-flex 57OC +19.0D Intraocular Lens
Product Usage: C-flex IOLs are designed to be surgically implanted into the capsular bag of the human eye as a replacement for the crystalline lens following phacoemulsification
Code Information: Batch 017100825 Lens #s: 01710082501, 01710082502, 01710082503, 01710082504, 01710082505, 01710082506, 01710082507, 01710082508, 01710082509, 01710082510, 01710082511, 01710082512, 01710082513, 01710082514, 01710082515, 01710082516, 01710082517, 01710082518, 01710082519, 01710082520, 01710082521, 01710082522, 01710082523, 01710082524, 01710082525, 01710082526, 01710082527, 01710082528, 01710082529, 01710082530, 01710082531, 01710082532, 01710082533, 01710082534, 01710082535, 01710082536, 01710082537, 01710082538, 01710082539, 01710082540, 01710082541, 01710082542, 01710082543, 01710082544, 01710082545, 01710082546, 01710082547, 01710082548, and 01710082549.
Recalling Firm/Manufacturer: Rayner Intraocular Lenses Limited
The Ridley Innovation Centre
10 Dominion Way
Worthing United Kingdom
Manufacturer Reason for Recall: Firm become aware of reports of post-operative refractive errors following implantation of lenses.
FDA Determined Cause: Error in labeling
Action: On August 31 the firm sent letters to all customers (health care facilities) that have received lenses in this batch and instructed to quarantine any remaining unused lenses from the C-flex 57OC +19.0D batch 017100825. Replacement, reimbursement or substitution is offered (as appropriate).
Quantity in Commerce: 49
Distribution: US in the states of MO

1 A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated.