Class 2 Device Recall Cflex Intraocular Lens

See Related Information[22]

Date Initiated by Firm	August 09, 2018
Create Date	September 28, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-3282-2018
Recall Event ID	80943[23]
PMA Number	P060011[24]
Product Classification	intraocular lens[25] - **Product Code** HQL[26]
Product	C-flex 570C +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 [2]	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 570C +19.0D batch 017100825. Replacement, reimbursement or substitution is offered (as appropriate).
Quantity in Commerce	49
Distribution	US in the states of MO
Total Product Life Cycle	*TPLC Device Report*[27]

[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.