FDA

Class 2 Device Recall ORA System with VerifEye

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Date Initiated by Firm	June 30, 2017
Create Date	August 21, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-3049-2017
Recall Event ID	77823[23]
Product Classification	intraocular lens surgery system[24] - **Product Code** NCF[25]
Product	ORA System with VerifEye+ Cart, Catalog Number 8065998307 For use during intraocular lens surgery
Code Information	Serial numbers:, C5013,C5014,C5015,C5016,C5017,C5018,C5019,C5020,C5021,C5023,C5024,C5025,C5026,C5027,C5028,C5029,C5030,C5031,C5032,C5033,C5034,C5035,C5036,C5038,C5039,C5040,C5041,C5042,C5043,C5044,, C5045,C5046,C5047,C5048,C5049,C5050,C5051,C5053,C5054,C5055,C5059,C5060,C5061,C5062,C5064,, C5065,C5066,C5069,C5071,C5075,C5076,C5077,C5078,C5079,C5080,C5081,C5082,C5083,C5090,C5093,, C5094,C5097,C5098,C5101,C5102,C5105,C5106,C5107,C5108,C5109,C5110,C5111,C5112,C5113,C5116,, C5117,C5119,C5120,C5121,C5122,C5125,C5126,C5127,C5128,C5129,C5130,C5131,C5132,C5133,C5134,, C5136,C5137,C5138,C5139,C5140,C5141,C5142,C5143,C5144,C5146,C5147,C5148,C5149,C5150,C5151,, C5152,C5153,C5154,C5155,C5156,C5157,C5158,C5159,C5160,C5161,C5163,C5164,C5165,C5166,C5167,, C5168,C5169,C5170,C5171,C5173,C5174,C5175,C5176,C5177,C5178,C5179,C5180,C5181,C5182,C5183,, C5184,C5185,C5186,C5187,C5188,C5189,C5190,C5191,C5192,C5193,C5194,C5195,C5196,C5197,C5198,, C5199,C5200,C5201,C5202,C5203,C5204,C5205,C5207,C5214,C5215,C5216,C5217,C5218,C5219,C5220,, C5221,C5222,C5223,C5224,C5225,C5226,C5227,C5228,C5229,C5230,C5231,C5232,C5233,C5238,C5239,, C5240,C5241,C5242,C5243,C5244,C5245,C5246,C5248,C5249,C5250,C5251,C5252,C5253,C5255,C5256,, C5257,C5258,C5259,C5260,C5261,C5262,C5263,C5264,C5265,C5266,C5267,C5268,C5269,C5270,C5271,, C5272,C5273,C5274,C5276,C5277,C5278,C5279,C5280,C5281,C5282,C5283,C5284,C5285,C5286,C5287,, C5288,C5289,C5290,C5291,C5292,C5293,C5294,C5295,C5296,C5297,C5298,C5299,C5300,C5301,C5302,, C5303,C5304,C5305,C5306,C5307,C5308,C5309,C5310,C5311,C5312,C5313,C5314,C5315,C5316,C5317,, C5318,C5319,C5320,C5321,C5322,C5323,C5326,C5328,C5329,C5330,C5334,C5335,C5336,C5339,C5340,, C5341,C5343,C5348,C5349,C5350,C5352,C5353,C5354,C5355,C5356,C5357,C5358,C5359,C5360,C5361,, C5362,C5363,C5364,C5365,C5366,C5368,C5369,C5370,C5371,C5372,C5373,C5374,C5375,C5376,C5377,, C5378,C5379,C5380,C5381,C5382,C5383,C5384,C5385,C5386,C5387,C5388,C5389,C5390,C5391,C5392,, C5393,C5394,C5395,C5396,C5397,C5398,C5399,C5400,C5401,C5402,C5403,C5404,C5405,C5406,C5407,, C5408,C5409,C5410,C5411,C5412,C5413,C5414,C5415,C5416,C5417,C5418,C5434,C5435,C5436,C5437,, C5438,C5439,C5440,C5441,C5442,C5443,C5444,C5446,C5448,C5449,C5451,C5452,C5453,C5454,C5456,, C5458,C5462,C5463,C5464,C5465,C5466,C5467,C5469,C5471,C5473,C5475,C5476,C5477,C5478,C5479,, C5484,C5485,C5486,C5487,C5488,C5489,C5490,C5493,C5494,C5495,C5496,C5497,C5499,C5500,C5501,, C5502,C5503,C5507,C5508,C5509,C5510,C5511,C5512,C5515,C5516,C5517,C5518,C5519,C5520,C5521,, C5522,C5524,C5525,C5526,C5527,C5528,C5529,C5530,C5532,C5533,C5534,C5535,C5536,C5537,C5538,, C5539,C5544,C5545,C5546,C5547,C5549,C5550,C5553,C5555 .
Recalling Firm/ Manufacturer	Alcon Research, Ltd. 6201 South Fwy Fort Worth TX 76134-2099
For Additional Information Contact	Wes Warnock 817-615-2501
Manufacturer Reason for Recall	Some ORA Carts have the potential to return an incorrect IOL power measurement during cataract surgery. This issue appears to have been caused by a software coding error that results in the lens coefficients for an IOL model being downloaded from the Alcon server in an incorrect order.
FDA Determined Cause [2]	Software design
Action	The Market Action was initiated with Initial telephone contact to all affected customers starting June 30, 2017. These customers were informed of the issue, and advised not to use their ORA Carts for calculations with the lens model affected on their specific system. A confirmatory letter (Attachment 4) was also sent via overnight mail to these customers July 12, 2017. As of July 12, 2017, Alcon has identified 8 ORA Carts that are affected by the software coding error. Alcon has reset the IOL databases on all 8 of the identified affected ORA Carts.
Quantity in Commerce	429 units

Distribution	Worldwide distribution. US Nationwide and Argentina, Australia, Belgium, Brazil, Canada, China, Colombia, France, India, Japan, Mexico, Netherlands, Panama, Portugal, Romania, Spain, Thailand, UAE, and United Kingdom
Total Product Life Cycle	TPLC Device Report[26]

[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. Learn more about medical device recalls[27].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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27. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm

Page Last Updated: 08/25/2017

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