Class 2 Recall Lumenis

See Related Information[22]

Date Posted	September 30, 2014
Recall Status[1]	Open
Recall Number	Z-2733-2014
Recall Event ID	69139[23]
Premarket Notification 510(K) Number	K130195[24]
Product Classification	Laser, Ophthalmic[25] - **Product Code** HQF[26]
Product	Array LaserLink, Manufactured by Lumenis, The Array" LaserLink" is a laser system accessory intended for use in the treatment of ocular pathology. " For the Posterior Segment, the Array" LaserLink" is indicated for use in Retinal Photocoagulation and Panretinal Photocoagulation of Vascular and Structural Abnormalities of the Retina and Choroid including: " Proliferative and Severe and Very Severe Non-Proliferative Diabetic Retinopathy " Macular Edema associated with Proliferative or Non-Proliferative Diabetic Retinopathy " Choroidal Neovascularization " Retinal Neovascularization associated with Retinal Occlusive Disease (Branch Retinal Vein Occlusion; Central Retinal Vein Occlusion) " Macular Edema associated with Branch Retinal Vein Occlusion " Retinal Tears and Detachments And Anterior Segments as follows: " Iridotomy in Closed Angle Glaucoma " Trabeculoplasty in Open Angle Glaucoma
Code Information	All assembled units since product release, Part Number: GA-0006700.
Recalling Firm/ Manufacturer	Lumenis, Inc. 3959 W 1820 S Salt Lake City, Utah 84104
For Additional Information Contact	Mr. Rick Gaykowski 801-656-2690
Manufacturer Reason for Recall	Lumenis initiated a field-correction for the Array Laser Link", GA-0006700 (SN XXYYZZ) because the system may project an erroneous pattern display on the retina, which is different than the desired pattern.
FDA Determined Cause [2]	DESIGN: Software Design
Action	Lumenis sent a Safety Advisory Notice dated July 15, 2014, to all affected consignees. The letter identified the product, the problem, and the action to be taken by the consignee. Consignees were instructed that Lumenis would contact consignees to schedule a product update, to be completed at a convenient time. For questions consignees should call 801-656-2549. For questions regarding this recall call 801-656-2690.
Quantity in Commerce	16
Distribution	Worldwide Distribution - USA (nationwide) and Internationally to JAPAN, CHINA, and CANADA.
Total Product Life Cycle	TPLC Device Report[27]