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Class 2 Device Recall Lumenis

Date Posted: September 30, 2014
Recall Status: Open
Recall Number: Z-2733-2014
Recall Event ID: 6913623
Premarket Notification 510(K) Number: K13019524
Product Classification: Laser, Ophthalmic - Product Code HQF

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: " 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 XXXYZZ) because the system may project an erroneous pattern display on the retina, which is different than the desired pattern.

FDA Determined Cause: 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 801-656-2543. 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

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=129733

10/14/2014