Class 2 Device Recall Lumenis M22 System

Recall Date: May 13, 2016
Recall Status: Open
Recall Number: Z-1669-2016
Recall Event ID: 73765
510(K) Number: K142860
Product Classification: Powered laser surgical instrument - Product Code GEX

Product: Lumenis M22 System Model Number: GA-0005400 (M22 IPL + YAG Module) with Acne Filter (KT-1014971).

Code Information: Lumenis M22 System Model Number: GA-0005400 (M22 IPL + YAG Module) All Acne Filters manufactured and Distributed Between: August 04 2015 and November 06 2015

Recalling Firm/Manufacturer: Lumenis Ltd
13 Hayetzira St, Yokneam Ind. Park
Yokneam Israel

Manufacturer Reason for Recall: Lumenis Ltd Announces a Field Action of the M22 IPL Acne Filters for the Lumenis M22 IPL Hand Piece due to the Risk of Superficial Burns When Using the Device.

FDA Determined Cause: Device Design

Action: Customers were notified on November 17, 2015 by Customer Notification Letter and customers were asked to return the device.

Quantity in Commerce: 33 filters

Distribution: Distributed in the states of GA, CA, CO, CT, KY, LA, MA, MN, NJ, NY, RI, and SC, and the countries of Italy, Germany, France, and China.

Total Product Life Cycle: TPLC Device Report

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 67.56
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database: 510(K)s with Product Code = GEX and Original Applicant = Lumenis Ltd

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm